11/21/2007

Draft for Discussion

Document # FACDQ11-03

Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs

Meeting #10

FDIC Seidman Center, Rooms 203 & 205

3501 Fairfax Drive, Arlington, VA

Wednesday – Friday, September 19-21, 2007

Draft Decisions at Meeting #10

*Note: Shaded votes are straw polls and not official votes taken by the Committee. The presentation reflects the order the recommendations were considered and voted on during the meeting.

1. Groundrules Amendment

The FACDQ agrees to amend the groundrules to include the following new and modified language:

In the absence of consensus, the committee will report its results as follows:

If the committee is evenly split, the committee will report different perspectives held on the issue, the rationale behind the perspectives, and the number of votes cast for each perspective.

If the voting tally shows a clear majority/minority split, the committee will report the majority position with perspectives and rationale and the number of votes cast and the minority position with perspectives and rationale and the number of votes cast.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

2. Meeting Summary #8

The FACDQ agrees to approve the meeting summary of Meeting #8 with the added language regarding the following notes:

- That no transcript was prepared from this meeting
- That all perspectives offered at the meeting are not reflected in the meeting summary.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

3. Meeting Summary #9

The FACDQ agrees to approve the meeting summary of Meeting #9 with the added language regarding the following notes:

- That no transcript was prepared from this meeting
- That all perspectives offered at the meeting are not reflected in the meeting summary.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

4. Uses Recommendations

A. Use #6 - Great Lakes Initiative (GLI)

The FACDQ agrees to approve Use #6 - Great Lakes Initiative (GLI) of the Uses Document as follows:

Recommendation: The FACDQ recommends that the FACDQ recommendations should not supersede the current Great Lakes Initiative provisions. The FACDQ believes that there is not a significant conflict between the FACDQ recommendations and the Great Lakes Initiative.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

B. Use #7 - Other Uses to Consider

The FACDQ agrees to approve Use #7 - Other Uses to Consider of the Uses Document as follows:

Decision: The FACDQ tabled the discussion on specific recommendations regarding the use of detection and quantitation for other uses including, but not limited to, the following:

- ambient monitoring 305(b)
- pretreatment
- non-regulatory operational monitoring
- stormwater monitoring
- other studies, such as fish tissues or biosolids characterization
- reasonable potential analysis
- effluent guidelines development
- limit derivation
- development of water quality criteria

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

C. Use #8 - Alternative Test Procedures

The FACDQ agrees to approve Use #8 - Alternative Test Procedures of the Uses Document as follows:

Recommendation: The FACDQ did not develop specific recommendations to EPA on updating the Alternative Test Procedures (ATP) Program. The FACDQ, however, does recommend that the ATP Program be updated to be consistent with recommendations from this document.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

D. Moving Use #1-#3 from the Uses Document

The FACDQ agrees to remove Uses #1-#3 from the Uses Document.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-20-07)*

APPROVED

E. ICIS Language

The FACDQ agrees to remove the following language from two places in Use #5 in the Uses Document:

"for purposes of updating 40 CFR Part 136 National Quantitation Limits."

Vote*: 16 Agree (Dave A., Bob A., Tim F., Tom M., Steve B., Richard B., Nan T., Roger C., Larry L., John P., Dave P., David K., Michael M., Rick R., Barry S., Mary S.*)**, 3 Not Opposed (***Cary J., Chris H., Jim P.*)**, 0 Disagree, 1 Absent (***Zonetta E.*)** *(9-20-07)*

APPROVED

F. Promulgation of QL_{nat}

The FACDQ recommends that EPA promulgate a QL_{nat} with the following minimum requirements:

1. EPA will use the DQO process to set MQO target MQOs for NPDES permit compliance testing.
2. A minimum of 6-7 labs.
3. Data collected at a minimum over 3- 6 months.
4. A minimum of 20 QL spikes used in the calculation of each single lab limit.
5. The data and lab be evaluated for validity prior to acceptance.
6. An appropriate outlier test is then applied to the dataset.

7. Evaluate the data for normality, using standard statistical tests.

8. If the data is normally distributed then calculate the upper 95% confidence limit, which becomes the $QL_{nat.}$

9. If the data is non-normally distributed then the 95th percentile QL_{lab} becomes the $QL_{nat.}$

10. EPA should then promulgate the newly calculated QL_{nat}.

***Straw Vote*: 8 Agree, 10 Not Opposed, 1 Disagree, 1 Abstain** *(9-20-07)*

G. Promulgation of QL_{nat}s for Existing and Future Methods (Formerly Use #4)

The FACDQ recommends that:

1. QL_{nat}'s be promulgated in a Part 122 table by analyte

2. EPA generate QL_{nat}s as rapidly as possible so that recommendation #TBD (current section 5 of the Uses Document) can be fully implemented.

3. QL's be promulgated only using the nationally promulgated approach.

4. Methods may be promulgated without promulgating a QL for that method. As new methods are proposed without a promulgated QL, data (eg: Single Lab Detection, Single Lab Quantitation, etc.) showing demonstrated method performance should be included in the method. The methods should include a statement that these performance levels are guidance and may not always be achievable.

Vote*: 16 Agree, 4 Not Opposed (Cary J., Nan T., Zonetta E., Chris H.***), 0 Disagree** *(9-20-07)*

APPROVED

H. Promulgation of QLs

The FACDQ recommends the following criteria be considered when EPA proposes the procedure for determining a QL:

1. EPA will use the DQO process to set target MQOs for NPDES permit compliance testing.

2. A minimum of 6-7 labs.

3. Data collected at a minimum over 3- 6 months.

4. A minimum of 20 QL spikes used in the calculation of each QL_{lab}.

5. The data and lab be evaluated for validity prior to acceptance.

6. An appropriate outlier test is then applied to the dataset.

7. Evaluate the data for normality, using standard statistical tests.

8. If the data is normally distributed then calculate the upper 95% confidence limit, which becomes the QL.

9. If the data are non-normally distributed then the 95^{th} percentile QL_{lab} becomes the QL.

Vote*: 9 Agree (Tom M., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P.*)**, 8 Not Opposed (***Dave A., Bob A., Steve B., Richard B., Cary J., Nan T., Michael M., Rick R.*)**, 1 Disagree (***Mary S.*)**, 2 Absent (***Tim F., Barry S.*)** *(9-20-07)*

NOT APPROVED

I. Use #5 Setting Permit Conditions, Reporting and Using Data, and Determining Compliance When the Water Quality Based Effluent Limit (WQBEL) is Less Then Detection and Quantitation Capabilities of Existing Methods

The FACDQ recommends that EPA implement Section #5 of the Uses Document as follows:

Recommendation: The FACDQ recommends that the following recommendations be incorporated into 40 CFR Part 122, as appropriate.

A. Recommendations for NPDES Permit and Compliance Uses When a National Quantitation Limit Exists

If the permitting authority requires use of a method more sensitive than the method for which a QL_{nat} exists, go to section B.

1. **Permit Requirements Related to Detection and Quantitation**

Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 122:

1. The default quantitation limit to be included in the permit or in rule as appropriate (Permit Quantitation Limit) is the Part 122 promulgated National Quantitation Limit unless the regulator determines that the Permit Quantitation Limit should be adjusted to account for sensitivity, selectivity, and/or matrix effects;

2. The permit shall contain a condition that the quantitation limit determined by the permittee's laboratory (Laboratory Quantitation Limit) shall be at or below the Permit Quantitation Limit. The permittee's laboratory may use any Part 136 method for which they can demonstrate a Laboratory Quantitation Limit at or below the Permit Quantitation Limit. If matrix effects have been given special attention in the permit then they would also have to be considered in compliance and enforcement.

3. The permit shall require the permittee to report the detection limit (Laboratory Detection Limit) and the Laboratory Quantitation Limit and maintain such information for a period of at least five years;

4. The permit shall require the permittee to maintain individual numeric results for a period of at least five years. The regulator may require the individual numeric result for any value that is greater than or equal to the Laboratory Detection Limit and less than the Permit Quantitation Limit be reported in a supplemental report.

5. The permit shall require that the Laboratory Detection Limit and the Laboratory Quantitation Limit be determined using the steps of the 40 CFR Part 136 procedure to establish the lowest possible value by the laboratory;

6. That EPA require the Laboratory Detection Limit, the Laboratory Quantitation Limit, and the Permit Quantitation Limit be reported by the regulator to the Integrated Compliance Information System

(ICIS).

2. **Establishing Compliance Thresholds and Determining Compliance**

Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 122:

1. Regulators will set average and daily maximum permit limits at the WQBEL.

2. Permittees must report to the regulator all information in the following manner on the Discharge Monitoring Report (DMR):

    i. To report daily maximum sample results:

    i. For values not detected at the Laboratory Detection Limit, report "not detected".

    ii. For values detected at the Laboratory Detection Limit but less than the Permit Quantitation Limit, report "detected less than the Permit Quantitation Limit".

    iii. For values greater than or equal to the Permit Quantitation Limit, report the actual numeric values.

    i. To report average sample results:

1. When all values used to calculate an average are not detected at the Laboratory Detection Limit, report "not detected".

2. When all values used to calculate an average are "detected less than Permit Quantitation Limit," report "detected less than the Permit Quantitation Limit."

3. When values used to calculate an average are a combination of "not detected" and "detected less than the Permit Quantitation Limit", report "detected less than the Permit Quantitation Limit".

4. When any value used to calculate an average is greater than or equal to the Permit Quantitation Limit, report the calculated numeric average after assigning zero to any individual value reported either as "not detected" or "detected less than the Permit Quantitation Limit."

3. To determine NPDES permit compliance with results reported on the DMR, regulators will:

    i. Determine that any daily maximum or monthly average results reported as either "not detected" or "detected less than the Permit Quantitation Limit" are in compliance with the effluent limitation.

ii. Compare any numeric results directly to the WQBEL

3. **Additional Permit Requirements**

Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 122: Permits shall include language that triggers additional steps when a "significant number" (to be determined in permitting process) of values detected at the Laboratory Detection Limit but less than the Permit Quantitation Limit are reported. These steps may include additional or accelerated monitoring, analytical studies such as matrix studies, pollutant minimization programs, or other permit conditions outside of the determination of compliance with effluent limitations. Reports under such provisions will be done outside of the DMR process, except that any additional effluent testing performed using approved analytical methods as part of the special studies must be reported on the DMR.

B. Recommendations for NPDES Permits and Compliance Uses When No National Quantitation Limit Exists, or if the Permitting Authority Requires a Permit Quantitation Limit lower than the National Quantitation Limit.

Recommendations:

1. In the absence of a National Quantitation Limit, the permitting authority is free to establish its process for determining compliance for analytes that have limits/water quality standards at a level lower than that which can be detected and/or quantified.

2. For a list of analytes as defined by EPA, the permit shall require that the Laboratory Detection Limit and the Laboratory Quantitation Limit be determined using the steps of the 40 CFR Part 136 procedure to establish the lowest possible value by the laboratory;

3. That EPA require the Laboratory Detection Limit and the Laboratory Quantitation Limit and the Permit Quantitation Limit be reported by the regulator to the Integrated Compliance Information System (ICIS).

Vote*: 12 Agree (Dave A., Bob A., Tom M., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Mary S.***), 4 Not Opposed (***Tim F., Richard B., Nan. T., Cary J.***), 4 Disagree (***Steve B., Michael M., Rick R., Barry S.***)** *(9-21-07)*

NOT APPROVED

5. Additional Recommendations

A. Additional Recommendation #3

The FACDQ agrees to approve the following Additional Recommendation:

"EPA continue to act as the national lead for Clean Water Act (CWA) programs in developing analytical methods and setting the performance standards for those methods."

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

B. Additional Recommendation #4

The FACDQ agrees to approve the following Additional Recommendation:

"EPA evaluate the federal resources dedicated to developing analytical methods with detection/quantitation limits of sufficient quality (i.e., meet data quality objectives) and capable of meeting the needs of CWA programs (e.g., quantitation at or below current water quality standards) and adjust those resources, where necessary, to meet data quality and program needs."

Vote*: 19 Agree, 0 Not Opposed, 0 Disagree, 1 Abstain (Mary S.***)** *(9-19-07)*

APPROVED

C. Additional Recommendation #7

The FACDQ agrees to approve the following Additional Recommendation:

"EPA develop and implement guidance on the new procedures as well as a computer-based program to assist in calculating detection and quantitation limits."

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

D. Additional Recommendation #1

The FACDQ agrees to approve the following Additional Recommendation:

"To maintain consistency and minimize effects on the environmental laboratory community, the FACDQ recommends that EPA programs that reference the present Part 136 Appendix B procedure consider adopting (the new procedure) that would replace it."

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

E. Additional Recommendation #2

The FACDQ agrees to approve the following Additional Recommendation:

"The FACDQ recommends that EPA's Office of Water complete a follow up pilot study to confirm the performance of the procedure(s) proposed for promulgation."

Vote*: 17 Agree, 3 Not Opposed (Tom M., Steve B., David K.*), 0 Disagree** *(9-19-07)*

APPROVED

F. Additional Recommendation #5

The FACDQ agrees to approve the following Additional Recommendation:

"EPA evaluate and modify the uses of data in CWA programs (beyond those uses discussed in the FACDQ recommendations) based on data uncertainty and decision error rate requirements relative to corresponding detection and quantitation limits. This could be accomplished through establishment of and adherence to data quality objectives for all CWA programs. How data relative to detection and

quantitation limits are to be used in 303(d) listings, reasonable potential determinations, NPDES effluent limit derivation, the development of water quality criteria, and other uses should be documented."

Vote*: 13 Agree (Dave A., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Michael M., Rick R., Barry S.*)**, 6 Not Opposed (***Bob A., Tim F., Tom M., Steve B., Richard B., Cary J.*)**, 1 Disagree (***Mary S.*)** *(9-20-07)*

NOT APPROVED

G. Additional Recommendation #6

The FACDQ agrees to approve the following Additional Recommendation:

"EPA establish data quality objectives (with indicators and measurement quality objectives) for CWA programs where detection/quantitation limits are used in decision making."

Vote*: 15 Agree (Dave A., Bob A., Tim F., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Michael M., Rick R.., Barry S.*)**, 4 Not Opposed (***Tom M., Steve B., Richard B., Cary J.*)**, 1 Disagree (***Mary S.*)** *(9-20-07)*

NOT APPROVED

H. Peer Review of the Procedure

The FACDQ recommends that a formal peer review take place for the FACDQ recommended procedure.

Vote*: 16 Agree, 4 Not Opposed (Bob A., Nan T., Zonetta E., Jim P.*)**, 0 Disagree** *(9-20-07)*

APPROVED

6. Single Lab Procedure Recommendations

A. Lab-Determined Detection Limits and Quantitation Limits (*As Is*)

The FACDQ recommends that EPA promulgate[1] the DQFAC Single Laboratory Procedure v2.4[2] recommended by the FACDQ for individual laboratories to determine their detection and quantitation limits. The DQFAC Single Laboratory Procedure v2.4 shall be used instead of the current MDL procedure in 40 CFR Part 136, Appendix B, for calculating all future Laboratory Detection and Quantitation Limits. The DQFAC Single Laboratory Procedure v2.4 has the following two capabilities:

- Demonstrates the lab's performance at a specified level.
- Determines the lowest possible value achievable by the lab while meeting the measurement quality objectives (MQOs).

***Straw Vote*: 9 Agree, 8 Not Opposed, 3 Disagree,** *(9/20/07)*

B. Lab-Determined Detection Limits and Quantitation Limits (*With Quick Resolution on Modifications*)

*Note: This vote reflects the Committee's desire to explore potential modifications and spend time on the language below:

The FACDQ recommends that EPA promulgate[1] the DQFAC Single Laboratory Procedure v2.4[2] recommended by the FACDQ for individual laboratories to determine their detection and quantitation limits. The DQFAC Single Laboratory Procedure v2.4 shall be used instead of the current MDL procedure in 40 CFR Part 136, Appendix B, for calculating all future Laboratory Detection and Quantitation Limits. The DQFAC Single Laboratory Procedure v2.4 has the following two capabilities:

- Demonstrates the lab's performance at a specified level.
- Determines the lowest possible value achievable by the lab while meeting the measurement quality objectives (MQOs).

***Straw Vote*: 10 Agree, 8 Not Opposed, 2 Disagree, 1 Abstained** *(9/20/07)*

C. Optional Batch Specific Verification

The FACDQ recommends that the following language be moved into the DQFAC Single Lab Procedure v2.4:

Blanks and QL spikes in each batch

1 The FACDQ recognizes that EPA cannot commit to promulgate the recommendations of the FACDQ without the benefit of public notice and comment. Wherever "promulgate" appears in the FACDQ recommendations, the FACDQ expects that EPA will propose a rule consistent with the FACDQ recommendations and then finalize a rule that fully considers those public comments.

2 This procedure was created via modifications to the ACIL.

1. If the method blank exceeds the DL and a cause cannot be identified, raise the DL to the blank result for future analysis

2. If the QL spike result (or QL spike times QL/spike level, if not spiking exactly at the QL) is less than the DL, elevate the QL by a factor of two and repeat the QL spike at the new QL. Repeat this until the QL spike is at or above the DL.

3. If the QL spike result is outside the average specified accuracy, elevate the QL by a factor of two and repeat the QL spike at the new QL. Repeat this until the QL spike meets the specified accuracy criteria.

Vote*: 4 Agree (Zonetta E., Chris H., Jim P., David K.***), 9 Not Opposed (***Richard B., Cary J., Nan T., Roger C., Larry L., John P., Dave P., Rick R., Barry S.***), 7 Disagree (***Dave A., Bob A., Tim F., Tom M., Steve B., Michael M., Mary S.***)** *(9-20-07)*

NOT APPROVED

D. Batch Verification

The FACDQ recommends that during promulgation, EPA include and/or develop language to incorporate batch specific verification as an option in the procedure.

Vote*: 16 Agree, 4 Not Opposed (Tom M., Richard B., Cary J., Mary S.***), 0 Disagree** *(9-20-07)*

APPROVED

E. QL Verification Frequency

The FACDQ recommends that the following be adopted into the DQFAC Single Lab Procedure v2.4:

Section 2.10 of the ACIL procedure specifies monthly QL verification spikes, evaluated on a quarterly basis. Section 2.2 of revised ACIL procedure specifies a minimum of quarterly QL verification spikes, evaluated on an annual basis. If we went to monthly QL verification spikes, evaluated annually this would provide a minimum of 24 QL spikes over a two year period to generate the long term estimate:

2.2 Continue to collect method blanks with each batch from which data were reported and QL spikes for every analyte[1] analyzed at least monthly (or four per twelve month period in separate batches

1 For multi component analytes a lab may use representative analytes to collect data for classes of compounds. When a representative analyte is monitored, the other analytes that compound represents must have similar sensitivity and method

spread across the time period during which analysis is conducted) which ever is greater. If multiple instruments are to be used for reporting data with the same DL and QL, analyze two to six QL spikes per instrument per twelve month period, so that a minimum of twelve QL spikes are generated each year.

2.2.1. Evaluate your DLs and QLs at least every year using all of the spikes available in a 24 month period using the procedures described in the Sections below. All method blanks and QL spikes collected within a 24 month period should be used for reassessing DLs and QLs, unless there is reason to believe that the DL or QL changed substantially at some point during that 24 month period. In that case the most recent data may be used for the reassessment, but not less than 20 method blanks and seven QL spikes per instrument.

Vote*: 4 Agree (Roger C., Larry L., John P., Dave P.***), 5 Not Opposed (***Zonetta E., Chris H., David K., Jim P., Rick R.***), 11 Disagree (***Dave A., Bob A., Tim F., Tom M., Steve B., Richard B., Cary J., Nan T., Michael M., Barry S., Mary S.***)** *(9-20-07)*

NOT APPROVED

F. QL Verification Frequency

The FACDQ recommends that EPA give additional consideration to increasing the frequency of QL verification and report its findings in the preamble of the Federal Register Notice and request specific comments on the final proposed frequency.

Vote*: 11 Agree, 9 Not Opposed (Bob A., Tim F., Tom M., Steve B., Richard B., Cary J., Nan T., Michael M., Mary S.***) 0 Disagree** *(9-20-07)*

APPROVED

G. DL Verification and Recalculation

The FACDQ recommends that the following be adopted into the DQFAC Single Lab Procedure v2.4:

Section 1.9 of the ACIL procedure specifies annual recalculation of DL and then uses an F test to determine if the DL should be revised. Section 2.2.2 (now 2.4) allows optional recalculation of the DL, with no decision criteria provided. By making the recalculation of the DL optional it is possible that the false positive error rate using the parametric statistical test could be greater than 1%.

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performance characteristics as demonstrated in initial DL/QL studies. If DLs or QLs for a monitored analyte are adjusted, as a consequence of on-going verification, the same adjustment must be applied to all analytes represented. An example is method 608 which includes several Aroclors, Toxaphene, and technical Chlordane. In this case, a mixture of Aroclors 1016 and 1260 might be used to represent all Aroclos. Toxaphene may be used to represent both Toxaphene and technical Chlordane.

2.2.2 Recalculate the DL using the formulas in 1.1.7. or 1.2.7.

Vote*: 8 Agree (Dave A., Roger C., Larry L., John P., Dave P., Zonetta E., David K., Jim P.***), 10 Not Opposed (***Bob A., Tom M., Steve B., Richard B., Cary J., Nan T., Chris H., Michael M., Rick R., Barry S.***), 2 Disagree (***Tim F., Mary S.***)** *(9-20-07)*

NOT APPROVED

H. Lab-Determined Detection Limits and Quantitation Limits

The FACDQ recommends that EPA promulgate[1] the DQFAC Single Laboratory Procedure v2.4[2] recommended by the FACDQ for individual laboratories to determine their detection and quantitation limits. The DQFAC Single Laboratory Procedure v2.4 shall be used instead of the current MDL procedure in 40 CFR Part 136, Appendix B, for calculating all future Laboratory Detection and Quantitation Limits. The DQFAC Single Laboratory Procedure v2.4 has the following two capabilities:

- Demonstrates the lab's performance at a specified level.
- Determines the lowest possible value achievable by the lab while meeting the measurement quality objectives (MQOs).

Vote*: 14 Agree (Dave A., Bob A., Tim F., Tom M., Steve B., Richard B., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Jim P., Rick R.***), 1 Not Opposed (***Chris H.***), 5 Disagree (***Cary J., David K., Michael M., Barry S., Mary S.***)** *(9-20-07)*

NOT APPROVED

7. Target MQO Bounds Recommendation

The FACDQ recommends that a single set of MQO bounds be established for promulgated Part 136 methods that define Quantitation for CWA compliance and enforcement uses.

Vote*: 7 Agree (Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P.***), 3 Not Opposed (***Dave A., Bob A., Tim F.***), 8 Disagree (***Tom M., Steve B., Cary J., Nan T., Michael M., Rick R., Barry S., Mary S.***), 2 Absent (***Roger C., Richard B.***)** *(9-21-07)*

NOT APPROVED

8. Matrix Effects Recommendations

A. Recommendation #1

The FACDQ recommends that EPA publish new guidance on matrix effects. At a minimum, the guidance should outline the appropriate level of matrix effects validation necessary for method promulgation for analytical methods to be considered for 40 CFR Part 136. The FACDQ recommends that EPA adhere to this guidance in methods it develops and validates for promulgation in 40 CFR Part 136. This guidance should also address the following:

- Determining the appropriate number of matrices to take into account.
- The level of validation required verses the proposed scope of use for the analytical method.
- Matrix effects validation in the ATP program.
- Impacts for consensus standards methods considered for part 136.

Vote*: 10 Agree (Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Barry S.*)**, 7 Not Opposed (***Dave A., Bob A., Tim F., Tom M., Cary J., Michael M., Rick R..*)**, 3 Disagree (***Steve B., Richard B., Mary S.*)** *(9-21-07)*

NOT APPROVED

B. Recommendation #2

The FACDQ recommends that EPA develop a consistent protocol on how to demonstrate matrix effects. The FACDQ believes such a protocol should be sensitive to cost and required level of effort to ensure that it is applied consistently.

Questions to be addressed by the protocol:

- What level of effort is necessary to determine if the matrix effects can be resolved by modifications of the analytical method that are within the flexibility allowed within the method?
- What set of experiments and data interpretation framework would suffice to demonstrate a matrix effect if performed properly?
- Who should be responsible for implementing a procedure to determine a matrix specific QL?
- How broadly applicable shall a matrix effect be considered? What level of demonstration should be considered adequate for a single facility? What level of demonstration should be undertaken to extend

the matrix specific QL to other like wastewaters?

Vote*: 13 Agree (Dave A., Bob A., Tom M., Richard B., Nan T., Roger C., Larry L., Dave P., John P., Zonetta E., Chris H., Jim P., Rick R.*), 6 Not Opposed (***Tim F., Steve B., Cary J., David K., Michael M., Barry S.*), 1 Disagree (***Mary S.*) *(9-21-07)***

NOT APPROVED

C. Recommendation #3

The FACDQ recommends that EPA develop a procedure for determining matrix-specific detection or quantitation limits for use where appropriate. Again, such a protocol should be sensitive to cost and required level of effort.

Questions that should be addressed include:

- Who should be responsible for implementing a procedure to determine a matrix specific QL?
- How broadly applicable shall a matrix effect be considered?

  What level of demonstration should be considered adequate for a single facility?

  What level of demonstration should be undertaken to extend the matrix specific QL to other like wastewaters?

Vote*: 11 Agree (Dave A., Tom M., Richard B., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., Jim P.*), 8 Not Opposed (***Bob A., Tim F., Steve B., Cary J., David K., Michael M., Rick R., Barry S.*), 1 Disagree (***Mary S.*) *(9-21-07)***

NOT APPROVED

D. Recommendation #4

When considering future updates of QL_{nat}, the FACDQ recommends that EPA take into consideration any experience with the performance in different matrices when considering a revision of the QL_{nat}.

Vote*: 11 Agree (Dave A., Tom M., Richard B., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., Jim P.*)**, 4 Not Opposed (***David K., Michael M., Rick R., Barry S.*)**, 5 Disagree (***Bob A., Tim F., Steve B., Cary J., Mary S.*)** *(9-21-07)*

NOT APPROVED

9. Verification Recommendation

The FACDQ recommends that the Verification Document be used as a resource document for the Single Lab DL QL Procedure v2.4 majority/minority report.

Vote*: 18 Agree, 2 Not Opposed (Zonetta E., Chris H.*)**, 0 Disagree** *(9-21-07)*

APPROVED

10. Implementation Recommendations

A. Recommendation #1

Although the FACDQ did not reach consensus on a procedure, we recommend that EPA act to develop an alternative to the current 40 CFR Part 136 Appendix B procedure. The results of the pilot study, and our evaluation of the ACIL modified procedure, indicate that there are deficiencies in the current 40 CFR Part 136 Appendix B procedure that can and should be corrected. The Single Lab DL QL Procedure v2.4 submitted contains elements that would be valuable to the agency in developing a new procedure.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-21-07)*

APPROVED

B. Recommendation #2

The FACDQ recommends that EPA develop guidance and outreach materials for stakeholders as EPA implements the FACDQ recommendations.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-21-07)*

APPROVED

11. Definitions Recommendations

A. Recommendation #1

The FACDQ recommends adding the IUPAC L_C, L_D, and L_Q definitions into the glossary.

Vote*: 13 Agree, 6 Not Opposed (Bob A., Tim F., Tom M., Richard B., Cary J., David K.*)**, 0 Disagree, 1 Absent (***Dave A.*)** *(9-21-07)*

APPROVED

B. Definitions: Detection Limits

The FACDQ recommends that the definitions for Detection Limits below be adopted for use in the Final Report:

DETECTION LIMIT (DL) – LAYPERSON'S DEFINITIONS

1. ***Detection Limit (DL) -*** *The minimum result which can be reliably discriminated from a blank (for example, with a 99% confidence level).*

2. **Detection Limit (DL)** – The lowest result that can be distinguished from the blank at a chosen level, α, of statistical confidence.

DETECTION LIMIT (DL) - STATISTICAL DEFINITIONS

1. **Detection Limit (DL)** - Smallest measured amount or concentration of analyte in a sample that gives rise to a Type I error tolerance of alpha under the null hypothesis that the true amount or concentration of analyte in the sample is equal to that of a blank. (The alternative hypothesis is that the true amount or concentration of analyte is greater than that of a blank.)

2. **Detection Limit (DL)** - The minimum observed result such that the lower 100 (1-)% confidence limit on the result is greater than the mean of the method blanks.

Vote*: 12 Agree, 7 Not Opposed (Steve B., Cary J., Zonetta E., Chris H., David K., Jim P., Mary S.*)**, 0**

Disagree, 1 Absent (*Barry S.***)** *(9-21-07)*

APPROVED

C. Definitions: Quantitation Limits

The FACDQ recommends that the definitions for Quantitation Limits below be adopted for use in the Final Report:

QUANTITATION LIMIT (QL) - DEFINITIONS

1. **Quantitation Limit (QL)**: The smallest detectable concentration of analyte greater than the detection limit (DL) where the accuracy (precision & bias) achieves the objectives of the intended purpose.

2. **Lab Quantitation Limit (QL_{lab})**: The smallest detectable concentration of analyte greater than the detection limit (DL) where the accuracy (precision & bias) demonstrated by the laboratory achieves the objectives of the intended purpose.

Vote*: 3 Agree (John P., Rick R., Mary S.***), 16 Not Opposed, 0 Disagree, 1 Absent (***Barry S.***)** *(9-21-07)*

APPROVED

12. Final Report Recommendation

The FACDQ approves the proposed process and schedule below for the Final Report of the Committee's work.

- The lead for each section will work with the designated back-ups to draft that section.
- The Final Report Work Group has some discretion over what goes into the appendices.
- As soon as a section is drafted, the lead will circulate it electronically to the caucuses for review and comment on a quick turn-around basis.
- Reviewers will be asked to send their comments on the initial draft via "tracked changes."
- The drafting team for each section will address those comments to the extent possible, accepting or rejecting the comments or making appropriate revisions, eliminating the "tracked changes."

- Before sending the draft to the Final Report Work Group, the lead will highlight any unresolved issues for Final Report Work Group discussion in **bold** type.
- The Uses Document was not a consensus document and it should be indicated as such in the main report with majority/minority perspectives.
- The Uses Document will be modified and included in the Appendix and will reflect the decisions made at the 10th FACDQ Meeting prior to being presented for a vote:
    - Moving Uses #1-#3 outside of the document.
    - The edits made on #4 prior to being voted on.
    - The edits to #5 prior to being voted on.

Proposed Schedule

- October 5: Majority/Minority Reports due to leads for the relevant section in the report
- November 9: Final Report Work Group sends first draft to the committee
- November 19: Submit comments back to Final Report Group.
- November 30: Final Report Work Group sends revised draft to the committee.
-

Details

- Use Microsoft Word, Times New Roman, font size 12
- Put section number and name in footer with the date of the draft (not autodates)
- Be precise about references; credit those that are used.

Vote*: 17 Agree, 0 Not Opposed, 0 Disagree, 3 Absent (Barry S., Jim P., Steve B.*) *(9-21-07)***

APPROVED

Day One – Wednesday, September 19, 2007, 9:00 AM – 7:45 PM

*Note: All perspectives offered at the meeting are not reflected in this summary however audio transcripts of the entire meeting are available.

Opening and Introductions

Richard Reding, EPA Designated Federal Officer (DFO), opened the meeting at 9:00 AM and welcomed participants. He then turned the meeting over to Alice Shorett, facilitator who initiated a round of introductions of advisory committee members and the facilitation team. All committee members were present, with one member participating by telephone.

Ms. Shorett recalled a common theme from the committee's first meeting in June 2005 when member statements of interest and measures of "success" showed a common desire "to make the situation better" and to get a better procedure. In the period since then, she said, the committee had come a long way towards that common goal. This meeting was the culminating event, when the committee would finalize its recommendations to EPA.

She concluded by asking members to use microphones and identify themselves when speaking so observers listening by teleconference could hear the proceedings. Ms. Shorett then turned the microphone over to Mary Smith of EPA.

Welcome from EPA

Mary Smith welcomed everyone and thanked them, on behalf of Michael Shapiro, Deputy Assistant Administrator for the Office of Water, for the tremendous amount of hard work committee members had put into the committee's process. She noted that this was the committee's tenth multi-day meeting. In addition, the Technical Work Group had had 68 conference call meetings, and the Policy Work Group had had 42 conference call meetings. Committee successes to date, she said, included coming to consensus on "What do we need a procedure to do," designing a pilot study, analyzing the data, and making significant progress on a "Uses" document.

The goal of this meeting, she said, was to come to consensus as much as possible on recommendations; where that was not possible, the committee would provide valuable input to EPA which intended to proceed to rule-making.

On a practical matter, she requested that committee members submit travel expenses promptly because it was the end of the federal fiscal year.

Agenda Review and Decision-Making Process

Facilitator Bob Wheeler said that the agenda for the day had been restructured to respond to three requests from pre-meeting calls with the caucuses. The requests were: to get the issues on the table early; to find out where committee members were on those issues; and to have a precise and structured decision-making process.

As a result, in the morning, brief presentations on the issues to be decided would be given, followed by opportunities for questions and clarifications. Over lunch, working in caucuses, members would discuss and decide on their positions. In the early afternoon, all members would go to work sheets (one for each recommendation under consideration), entitled, "Where are you?" that were placed on the walls around the room. They would indicate "where they were" on each recommendation by putting a dot for each recommendation:

- Green dots to signal agreement,
- Yellow dots to indicate they had questions or were unsure of their position, or
- Red dots if they opposed the recommendation.

The sheets also provided space for comments, allowing members to indicate concerns or changes needed to allow them to support the recommendation.

The purpose of this approach, Mr. Wheeler said, was for the committee to be able to see, quickly and easily, where the committee had reached consensus, where additional work was needed, and/or where differences existed that were unlikely to be overcome. Decision-making would begin with areas where agreement was clear and move later to those requiring more discussion. The goal was to complete recommendations on the issues during the afternoon and evening, even if this meant moving the scheduled discussion of the procedure to Day Two.

Groundrules Amendment

Mr. Wheeler then presented the facilitation team's response to the committee's request for a structured, clear decision-making process. He said the facilitators were proposing a revision to the committee's existing groundrules related to reporting results when consensus was not achieved. The proposal was to present actual voting tallies, whether the committee was evenly split or there was a majority/minority vote. The facilitators also proposed that majority and minority reports be prepared to present the rationales for the votes and that the key points and individuals or teams who would be responsible for drafting the rationales for the Final Report be identified during the meeting.

In the discussions that followed, John Phillips asked how much extra time it would take to document individual votes while Nan Thomey recommended showing votes by caucus. After discussion, it was agreed that votes would be kept by individual during the meeting and that the Final Report Work Group would translate individual results into "caucus" votes.

With respect to the majority/minority rationales and authors for them, it was agreed that those in the majority would write the majority opinion and those in the minority would write the minority opinion. The authors or teams for each perspective would be identified immediately after the vote as would the key points for or against, as input to the writing that would occur after the meeting.

The committee voted unanimously for the amended groundrule on reporting its results.

Groundrules Amendment
The FACDQ agrees to amend the groundrules to include the following new and modified language:
"In the absence of consensus, the committee will report its results as follows:

If the committee is evenly split, the committee will report different perspectives held on the issue, the rationale behind the perspectives, and the number of votes cast for each perspective.

If the voting tally shows a clear majority/minority split, the committee will report the majority position with perspectives and rationale and the number of votes cast and the minority position with perspectives and rationale and the number of votes cast."
***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*
APPROVED

Meeting Summaries

Meeting #7, June 6-8, 2007

Mr. Wheeler introduced document #2 (Draft Mtg Sum #7) and asked the committee for comments. Michael Murray requested that a sentence be added to meeting summaries to indicate that some committee decisions were made, not by a formal vote, but rather as a collective nodding of heads or "sense of the committee" to move forward in a particular direction. He also recommended adding a sentence to indicate that the summaries did not record all of the comments and perspectives offered at meetings. Finally, he asked about the identity of a group referenced on p. 36.

John Phillips asked about the process for preparing the meeting summaries and if transcripts were made of the meetings. Larry LaFleur commented that the meeting summaries were uneven. They captured detailed discussions in some places but not in others; as a result he felt that they did not reflect the committee's discussions. Mr. LaFleur then pointed out a place on page 36 where a sentence that preceded a series of "boxes" ("actions" and votes) should have been included in the boxes but was not. (Mr. LaFleur's issue was later cleared up and no change was made to the summary.)

After these comments, Mr. Wheeler said that the facilitation team would add a sentence to explain what shaded text meant, check on the items to be corrected, indicate where transcripts were available, and bring this summary to the December meeting for approval. At a later point in the meeting, Ms. Smith said she would need to check but she thought that audio tapes of committee meetings could be made available at the docket.

Meeting Summary #8 (July 25, 2007 Teleconference Meeting)

Michael Murray said that a clarification on p. 2 would be helpful, to indicate which two numbers Richard Burrows had intended. (The sentence in question read: *Response (Richard Burrows):* The QL_{nat} puts a ceiling on a DL_{nat}; a DL_{nat} cannot be within a certain range of a QL_{nat}. There is no benefit to having two numbers.) Mr. Burrows clarified that he had intended the two numbers to be a DL_{nat} and a QL_{nat}.

On page 4, section 5, third paragraph, a sentence was amended to read as follows: "where methods cannot analyze at levels sufficient to assess the ability to meet water quality criteria."

Page 5, first paragraph, Steve Bonde asked if the summary of Ms. Smith's comments were accurate. In response, Mary Smith said that it did convey what she had said and that it was her understanding that analytical capabilities were taken into account when setting MCLs.

Mr. Wheeler said the meeting summary would note that no transcript had been made of the teleconference meeting and the two changes Mr. Murray had requested would be made.

The committee voted by consensus to approve the summary with the indicated changes.

Meeting Summary #8

The FACDQ agrees to approve the meeting summary of Meeting #8 with the added language regarding the following notes:

- That no transcript was prepared from this meeting
- That all perspectives offered at the meeting are not reflected in the meeting summary.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

Meeting Summary #9 (August 28, 2007 Teleconference Meeting)

Mr. Wheeler indicated that the teleconference meeting was not recorded and no transcript had been made.

There were no changes or comments. The committee voted by consensus to approve the summary.

Meeting Summary #9

The FACDQ agrees to approve the meeting summary of Meeting #9 with the added language regarding the following notes:

- That no transcript was prepared from this meeting

- That all perspectives offered at the meeting are not reflected in the meeting summary.

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*

APPROVED

Caucus Reports

Environmental Laboratories: Richard Burrows reported that he, Larry LaFleur, Mary Smith and Nan Thomey had attended the National Environmental Monitoring Conference (NEMC) and presented on various aspects of the committees work, with about 300 people in the audience.

Environmental Community: Rick Rediske reported that he had sent the procedure to four research laboratories involved in trace organic work and all four had felt it would not be a problem to implement the procedure.

Industry: No report

Public Utilities: David Kimbrough said that he had met with California's Lab Accreditation Group in June and had gotten comments but that the procedure had changed since then so he had no report.

States: Bob Avery said he had sent the Procedure and Uses document to all of the state laboratory directors but had received only one response, from New Mexico. That response asked how it would tie in with Part 141 (Drinking Water Act) and wanted to see a longer discussion of the applicability of blanks. The response asked why k was used as a multiplier rather than the "Student t". Mr. Avery said that he had also talked to a number of private laboratory directors who asked that someone "tell us what you want us to do and we will tell you what we think." Private laboratories, he said, were worried and did not want to do two or three different procedures. He also asked what would happen if others did not follow the committee's lead? He said states would be left spending more resources at higher cost and that if we cannot get buy-in, this will come out in the public comment period.

EPA: Mary Smith noted that implementation issues had come up at the NEMC. She also said that EPA had been meeting internally because the agency was not unanimous on all FACDQ issues. In response to a request made by a committee member at the June FACDQ meeting, she said, Brad Venner of EPA's Office of Enforcement and Compliance Administration (OECA) was at the meeting to give OECA's position on the issues the committee was dealing with. Before speaking on his issues, Mr. Venner confirmed that senior management had reviewed his remarks and that he would be giving OECA's official position.

Target MQO Bounds, by Brad Venner

Mr. Venner provided a six-page handout to the committee, presenting OECA's position. He said he would focus his remarks on Target Measurement Quality Objectives (MQO) Bounds. OECA's concern, he said, was that if these "bounds" were published, they would likely be interpreted as defining the limits of reliable measurement. If a method could not meet these bounds at any concentration, it would mean that some pollutants could not be regulated or even measured at current levels.

Instead of Target MQO Bounds, he said that what OECA would like to see would be further development of guidance on using the Data Quality Objectives (DQO) Process. In the DQO process, an approach is developed that considers the basic DQOs for the problem and uses the DQO process to set MQOs. In other words, the essential quality of data should be driven by decisions to be made on the basis of the data. This approach, he said, would allow different MQO Bounds for different pollutants, depending on the water quality criteria. He provided several illustrations for how this process could work (p. 3-5 of the handout). He also expressed concerns about the committee's draft recommendation not to report numerical values on the Daily Monitoring Reports (DMRs) (p. 5-6) and the substitution of zero for values below QLs (p. 6).

Instead of these approaches, he said that OECA supported a "flexible and dynamic evaluation of measurement uncertainty" (p.6). The measurement uncertainty for individual results would be calculated and reported along with the result. OECA felt that EPA data systems should be modified to allow recording of this information in the database.

Mr. Venner then asked for questions and the committee entered a discussion of OECA's position.

Discussion

Question: John Phillips asked if having a QL greater than a DL was a bound.

Response: Mr. Venner agreed that it was.

Comment: Michael Murray said that the OECA's approach, in contrast to using 0 in averaging, seemed reasonable. He said he liked the decision criterion being relative to the regulatory limit versus how Detection compares to the true value of zero. He also said that some on the committee had raised some of Mr. Venner's concerns early in the committee process.

Comment: David Kimbrough said that basing MQOs on end uses, as OECA proposed, was a problem on a practical level because there were different needs for Reasonable Potential Assessments (RPAs) and for compliance.

Response: Mr. Venner said that OECA wanted EPA to move toward estimating measurement uncertainty for a particular measurement so one could decide what the data could be used for.

Question: Richard Burrows asked, when using the DQO process (regardless of use), how one could set a general accuracy and precision when specific MQOs depended on a result for a specific effluent.

Response: Mr. Venner agreed and said that QL,'s were the place where certain accuracy and precision could be achieved. Where QL would be set should depend on where the regulatory standard was. An example, he said, was PCBs where Water Quality Criterion is essentially zero. If one got a detect, it was over the standard.

Comment: Tim Fitzpatrick added that setting MQOs based on regulatory standards works when limits are fixed but they often aren't; they depend on water bodies. It was not a simple task of looking at the regulatory limit.

Response: Mr. Venner agreed. He said WQBELS needed to be based on the receiving water. He also said that OECA preferred for labs to identify numbers with their uncertainty.

Question: Tim Fitzpatrick asked if it would be acceptable to report a DL limit and uncertainty related to a number near the DL or a multiplier greater than the DL?

Response: Mr. Venner said that the notion of QL with MQO Bounds was not a good approach and that OECA was against a binary approach.

Comment: David Kimbrough said that the idea of having a QL for each water body was tempting but what did that mean, practically speaking, especially if a lab got samples from all over (the state, the region, the nation) and it had to give information to the permittee. With respect to "binary," Mr. Kimbrough said that it was a reality: either a permittee was in compliance or it was not. He also commented that the Poisson model (for radiochemistry and asbestos) was not a good one because it was not one we use.

Comment: Dave Akers pointed out that if one were to try to make greater use of uncertainty, it would require state regulators to have greater expertise and more staffing. He also pointed to examples when samples were taken and analyzed and were expected to be reported within a certain period. If reporting was going to be in a different period than the sampling, regulators would have to make changes.

Response: Mr. Venner said that results could always be reported. He said that OECA recognized there was a gray area. In cases where one could not make a determination, then perhaps special things would follow.

Question: Larry LaFleur noted that the idea for the MQO Bounds had been to set a floor for MQOs after the committee backed away from specific MQOs. Other than a fixed floor, he asked if the DQO process should be allowed to continue until one got to an uncertainty interval at zero?

Response: Mr. Venner said that this was what OECA would like to see. This approach lets OECA avoid not being able to regulate analytes with very little recovery or precision in a concentration by instead targeting the regulatory limit. The DQO process would say: the goal of making this decision is make sure you don't make a False Positive decision. The goal of the DQO process would be to make sure we are not chasing after false positives.

Comment: Nan Thomey said it was hard for her to see how to process this input at the committee's decision-making meeting. What the committee has been trying to do, she said, has been to develop a solution that has the advantage of being a procedure labs can afford to generate results at a time and a cost that permittees can afford. She said that zero uncertainty was not affordable and we needed something that could be practically implemented. She asked how much effort OECA had put into assessing the cost for labs to generate these results.

Response: Mr. Venner said he understood that the analytical community did not agree but that accreditation standards were moving toward this. His proposal would build on the DQO process and that burden would fall on states rather than labs.

Comment: Tim Fitzpatrick said that if one moved away from RCRA, where a single number was applicable everywhere, he liked the concept of looking at uncertainty in the instrument with the practical impact for labs for Clean Water Act programs being to model the uncertainty because different standards exist for different water bodies and different states. Every result would have an uncertainty associated with it. It would be useful to have it across the whole calibration range but that would be beyond the average lab.

Response: Mr. Venner replied that one way would be through an interlaboratory procedure; it would not be lab specific. It would not require a complex process

Comment: Mr. Burrows added, in response to Mr. Fitzpatrick's comments, that the new procedure would give accuracy and precision at the QL at a reasonable cost. We can report our accuracy and precision at the QL which might give preference to labs that can get better data.

Response: Mr. Venner agreed.

Brief Presentations of Proposed Recommendations

After a break, the committee reconvened at 11:05 AM to hear brief presentations on the key features or changes to recommendations that had occurred since the committee's June meeting.

Uses Document

Dave Akers said that the Uses document reflected changes that he and Mary Smith had made for the readability of the Final Report. Their approach had been to remove Recommendations #1 (Procedure recommendation), #2 (Matrix Effects), and #3 (Verification) from the Uses document because they were not Uses and to insert them in the section on the procedure recommendation since they were more closely associated with the procedure.

Consequently, Mr. Wheeler said, the discussion of the Uses document would focus on Recommendations #4 - #8.

Use #4, Promulgation of National Quantitation Limits Recommendation

Mr. Wheeler noted that three alternatives had been developed for Recommendation #4. At the request of the Policy Work Group, Larry LaFleur and Tom Mugan had undertaken to separate the choices embodied in the three alternatives and to respond to basic questions that Richard Burrows had posed. (A matrix presenting the choices was projected before the committee during the discussion.) The intent was to allow the committee to understand the choices and to decide which combination made the most sense.

The basic questions to be considered were as follows:

- Do we want QL_{nat} analyte or method/analyte based?
- Do we want QL_{nat} in the method or in a separate table?
- Do we want QL_{nat} only for analytes with water quality criteria below the capability of the method or for other analytes as well?
- Do we want QLmethod and QL_{nat}?
- Should a QL_{nat}/method be required for method promulgation?

Use #6, Matrix Effects

Larry LaFleur said this recommendation was general rather than specific. It identified four issues for EPA to address in guidance rather than regulation to preserve flexibility.

Use #7, Verification

Michael Murray said he had worked with David Kimbrough and Richard Burrows on a general recommendation with two alternatives, the second of which offered more specifics. After learning that the procedure included a verification process, the work group had revised the recommendation to address the situation if the committee failed to reach consensus on a procedure or if the procedure recommended did not have a verification section, and, in those cases, proposed that EPA should proceed with a verification process.

Implementation Issues

Nan Thomey, who had lead the Implementation Work Group, referenced meeting documents (8) Implementation Timeline, (9) Implementation Process Schematic, (10) (Implementation Guidance and Education), and (11) Implementation Recommendations. She observed that concerns over implementation and perceived difficulties and differences in implementation were what had led to three alternatives for $Ql_{nat}s$ (discussed above). She said that the Implementation Work Group had concluded it needed to answer questions before it could decide on recommendations, which had led to documents #8 - #10. Mary Smith had posed a set of questions based on the information the Work Group had developed and these questions are embodied in the Implementation Recommendations. She said the Work Group proposed including documents #8 – #10 as non-consensus attachments to the Final Report.

Additional FACDQ Recommendations

Seven additional recommendations were included as document (12) Additional FACDQ Recommendations within the committee's packet of materials. Mr. Wheeler asked the sponsor of each recommendation to describe the intent. The descriptions follow:

1. Steve Bonde said it was intended to address laboratory concerns over multiple DLs and the resulting cost and confusion they could create.

2. John Phillips said industry strongly believed that a long-term evaluation of the procedure was needed.

3. Jim Pletl proposed that the FACDQ recommend that EPA continue to lead for Clean Water Act programs.

4. Mr. Pletl said this recommendation addressed the need for appropriate resources to develop methods and wanted EPA to step back and look at all of the human health and environmental programs.

5. Mr. Pletl noted that the Uses document addressed only data uncertainty below WQBELs; this

recommendation addressed data uncertainty below QLs.

6. Mr. Pletl said this proposal asked the FACDQ to recommend that EPA take the next step beyond the DQO Guidance document (EPA Guidance on Systematic Planning Using the Data Quality Objectives Process) to have DQOs and Data Quality Indicators (DQIs).

7. Mr. Pletl said this recommendation addressed the need for guidance on procedures and a computer-based program to help small laboratories.

QL_{nat} Determinations

Richard Reding reported that a subgroup had met four times but not all caucuses had been able to participate consistently. The group had divided its recommendations into two parts -- those for new methods and those for future updates to existing methods -- and had proposed general ideas about the number of labs and replicates.

Target MQO Bounds

While noting that the title seemed to be an oxymoron, John Phillips said that the word "target" was to contrast with "fixed" MQOs. He noted that the committee had failed to reach agreement on fixed MQOs and that a work group had made another attempt, through this recommendation, to address data uncertainty. The work group had determined that MQO Bounds was not just a technical question; it was also a policy decision. He acknowledged that the group had not reached consensus on the recommendation which was intended to set a floor and a ceiling on data and data acceptability for regulatory programs. The recommendation proposed having EPA use the DQO process to set MQOs.

Questions of Clarification Related to the Recommendations

Uses #4, Alternatives

Mary Smith asked for clarification on the options in the matrix for Uses #4 as follows:

- How would Water Quality Criteria, Water Quality Standards and WQBELs be factored into the alternatives?
- On a practical level, how would a permit writer figure out how to write the permit?

Larry LaFleur said that the intent of the matrix was to separate out the issues that related to a table.

Alternative 1 would apply only to future methods; Alternative 2 would apply in the case of low Water Quality Standards (to support the WQBEL permitting strategy the committee had proposed) and also address prioritization of existing methods; and Alternative 3 would address all future methods and EPA's prioritization of existing methods.

In response to Ms. Smith's question about how Alternatives 2 and 3 would work in practice, Mr. LaFleur responded that in the case of Alternative 3, when EPA promulgated a new method, it would put a QL in the method. At the same time, EPA might want to put it in a table (Part 122) to show it was the best. There was some discussion about how this would work in practice, especially if there were two competing methods. Mr. Mugan added that the QL had to be based on the method that EPA considered the most sensitive. In the table, EPA could say which method it had used to develop the QL.

Ms. Smith asked about the case when two methods were similar and close and the WQBELS were all over the place, which one would be picked. Mr. Mugan replied that he had proposed a QL by analyte and by method to address that circumstance, to provide useful data for a permit writer. Mr. Burrows added that best professional judgment would also come into play in these decisions. So long as the permitting process identified a number for the labs, the labs could choose an appropriate method.

Mr. LaFleur said that the intent of the table was to enact the permitting strategy the committee had developed and to make that strategy obvious. The additional work that would be needed was only for the Part 122 table.

Mr. Burrows said that Alternative 2 grew out of practical considerations related to how long it could take to establish QL_{nat}s; it would not require a QL_{nat} in a method for it to be put into Part 136. With respect to a QLmethod, he said he did not think a QLmethod would require the same rigor as a QL_{nat}. He said it would be nice to have QL_{nat}s for everything but questioned if that was practical.

Ms. Smith said her biggest concern was picking the number because the agency could always be sued. She said her approach, in the case of analytes for which Water Quality Criteria were very low and there were many method choices, would be to pick the most sensitive method. With respect to cases where WQBELS were not as low and there was variability across the states, she would consider the array of QLs and pick the lowest one.

Mr. LaFleur agreed that the table should be populated with the most sensitive methods. He also said it would be up to the permit writer to pick the number.

Discussion continued on questions related to the information in the matrix of alternatives and possible combinations of the alternatives.

Implementation

Cary Jackson began by complimenting the Implementation Work Group's results. He recommended that the proposed outreach and education approaches should go further. If EPA proposed a change, it needed to conduct outreach to stakeholders at that point so they could comment intelligently. He recommended the comment period be extended to 180 days, to provide ample time, and options for publicity included publications, seminars and the website. Outreach should be conducted both on what was proposed and what was to be promulgated.

Other Issues

- Bob Avery expressed a concern that, in the end, the QL_{nat} would become the highest common denominator.
- With respect to setting a floor for QL_{nat}s, Michael Murray said that QL_{lab}s had to be below QL_{nat}s. It was not essential that every lab be able to analyze every pollutant. He said it was important to set floors for WQBELS.
- Mr. LaFleur agreed that a requirement in the Uses document was for the QL_{nat} to put a cap on a lab's performance. In updates, he said, EPA could lower QL_{nat}s as performance improved.
- Mr. Avery commented that if the verification process were to be on-line, then every program would have to meet the Part 122; it would need to exclude other programs.
- Mr. LaFleur said that he understood verification would be written into Part 122 to support the permitting strategy. It did not imply it would apply anywhere else in the permitting process.
- Mr. Murray said that it was important to capture that the purpose of QL_{nat} if it is removed from the Uses document.
- Mr. Burrows clarified that while the QL_{nat} would go into a permit, the permittee would have to use a lab that could meet the QL_{nat}.

Ms. Smith asked Mr. Pletl what was the concern behind Additional Recommendation #3. Mr. Pletl noted that EPA had begun looking at privatization over the past five years and that this approach worked sometimes but sometimes it did not. He said he wanted EPA to continue to lead the program, interpreting regulations, and developing new methods with input from private, municipal and state labs.

At 12:45 Mr. Wheeler provided instructions for caucus work over lunch and directions on how to place dots and provide comments on the recommendations worksheets around the room (Dots for Cary Jackson, attending the meeting via teleconference connection, would be placed after consultation with Cary by his caucus members).

At 2:35 the committee reconvened. Based on a quick scan of the green, yellow and red dots on the worksheets, Mr. Wheeler proposed, and the committee agreed, to begin work on the recommendations that had the most agreement (based on number of green dots and lack of red dots) and work down through those with less agreement (fewer green dots, more yellow dots and/or red dots) as follows:

- Uses #6 – 8
- Additional recommendations 3, 4 and 7
- Implementation
- Additional recommendations 1 and 2
- Uses #4 and #5
- Matrix Effects
- Target MQO Bounds
- QLnat

Mr. Wheeler said that the goal was for the committee to make final decisions on this set of issues and recommendations on Day One. Depending on how much time it took to make decisions on this set of issues, he said that work on the procedure and definitions would likely be moved to the agenda for Day Two.

The proposed process that the committee approved was to review the results (dots and written comments) on each worksheet, have discussion, and make decisions. In every case, the language to be voted on would be projected before the committee, so it was clear what the committee was voting on. If the committee needed

caucus time before votes, it would be provided.

Vote on Uses #6: Great Lakes Initiative (18 Green Dots)

The worksheets indicated unanimous support for this recommendation. The committee approved the recommendation by consensus.

Use #6 - Great Lakes Initiative (GLI)
The FACDQ agrees to approve Use #6 - Great Lakes Initiative (GLI) of the Uses Document as follows:
Recommendation: The FACDQ recommends that the FACDQ recommendations should not supersede the current Great Lakes Initiative provisions. The FACDQ believes that there is not a significant conflict between the FACDQ recommendations and the Great Lakes Initiative.
***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*
APPROVED

Uses #7: Other Uses to Consider (15 Green Dots, 1 Yellow Dot)

Jim Pletl noted that #7 reflected a committee decision rather than a recommendation and the committee agreed to replace the word "recommendation" with "decision." After discussion about the list of the issues, it was agreed to add the word "specific." With that change, the committee voted and approved the recommendation by consensus.

Use #7 - Other Uses to Consider
The FACDQ agrees to approve Use #7 - Other Uses to Consider of the Uses Document as follows:
Decision: The FACDQ tabled the discussion on specific recommendations regarding the use of detection and quantitation for other uses including, but not limited to, the following:

- ambient monitoring 305(b)
- pretreatment
- non-regulatory operational monitoring
- stormwater monitoring
- other studies, such as fish tissues or biosolids characterization
- reasonable potential analysis
- effluent guidelines development
- limit derivation
- development of water quality criteria

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*
APPROVED

Uses #8: Alternative Test Procedures (18 Green Dots)

In response to Mr. Murray's question if the two sentences in the recommendation were compatible, Mr. Fitzpatrick recommended revising the language to read that the FACDQ "did not develop." With this change, the committee voted and approved the recommendation by consensus.

Use #8 - Alternative Test Procedures
The FACDQ agrees to approve Use #8 - Alternative Test Procedures of the Uses Document as follows:
Recommendation: The FACDQ did not develop specific recommendations to EPA on updating the Alternative Test Procedures (ATP) Program. The FACDQ, however, does recommend that the ATP Program be updated to be consistent with recommendations from this document.
***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*
APPROVED

Additional Recommendation #3 (20 Green Dots)

Mary Smith noted that this thought might be captured in the Final Report.

The committee voted and approved the recommendation by consensus.

Additional Recommendation #3
The FACDQ agrees to approve the following Additional Recommendation:
"EPA continue to act as the national lead for Clean Water Act (CWA) programs in developing analytical methods and setting the performance standards for those methods."
***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*
APPROVED

Additional Recommendation #4 (19 Green Dots, EPA Abstention)

Mary Smith said it was improper for EPA to vote on a funding recommendation. She therefore abstained.

The committee voted in favor of the recommendation with 19 agreeing and one abstention.

Additional Recommendation #4
The FACDQ agrees to approve the following Additional Recommendation:
"EPA evaluate the federal resources dedicated to developing analytical methods with detection/quantitation limits of sufficient quality (i.e., meet data quality objectives) and capable of meeting the needs of CWA programs (e.g., quantitation at or below current water quality standards) and adjust those resources, where necessary, to meet data quality and program needs."
***Vote*: 19 Agree, 0 Not Opposed, 0 Disagree, 1 Abstain (*Mary S.*)** *(9-19-07)*
APPROVED

Additional Recommendation #7 (19 Green Dots)

The committee voted and approved the recommendation by consensus.

Additional Recommendation #7
The FACDQ agrees to approve the following Additional Recommendation:
"EPA develop and implement guidance on the new procedures as well as a computer-based program to assist in calculating detection and quantitation limits."
***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*
APPROVED

Implementation (Document #11) (14 Green Dots, 6 Yellow Dots)

During discussion, several questions and issues were raised, including:

- Reporting results not just when the WQBEL is *below* the QL (as currently recommended) but also when it is *above* because the data could potentially be useful for other purposes
- A need for clarification of some of the points in the list of questions

Ms. Thomey said her Work Group had needed to bring something to the FACDQ despite the fact that decisions had not been made. Now that decisions were being made, she recommended returning to implementation after more decisions have been made.

After discussion about the intent of and expectations for meeting document #11, John Phillips suggested that the title of document #11 be revised to read Implementation Considerations. The committee agreed to the title change and to return to implementation issues later in the meeting.

Additional Recommendation #1 (13 Green Dots and 6 Yellow Dots)

Mary Smith said that EPA could not vote for this recommendation on behalf of other programs, such as Drinking Water and Solid Waste. Several changes were made to the recommendation during discussion, including replacing "adopt" with "consider," identifying that the new procedure had been considered by a group of Clean Water Act stakeholders, and identifying a goal of minimizing impacts on the environmental laboratory community.

The committee voted on the recommendation as revised and approved it by consensus.

Additional Recommendation #1
The FACDQ agrees to approve the following Additional Recommendation:
"To maintain consistency and minimize effects on the environmental laboratory community, the FACDQ recommends that EPA programs that reference the present Part 136 Appendix B procedure consider adopting (the new procedure) that would replace it."

***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-19-07)*
APPROVED

After the vote and assuming that the committee reached consensus on a procedure recommendation, Ms. Thomey suggested that the Final Report Work Group could insert the committee's recommended procedure recommendation into this recommendation.

Additional Recommendation #2 (14 Green Dots, 3 Yellow Dots, 1 Red Dot)

The committee discussed a number of issues related to this recommendation including the facts that,

- The committee hadn't yet recommended a procedure so it was unknown what would be studied
- The ACIL modified procedure tested in the pilot study had changed since the pilot study and, consequently, had not been tested
- Such a study would be appropriate even if the MDL were kept because it had not been tested
- Such a study should be conducted and that it should, moreover, include QL_{nat}s, to test if the individual lab results made sense with QL_{nat}s
- "Long term" had not been defined and resources were an issue and
- It was not clear how it would work to conduct a confirmatory study after the procedure was in regulation
- The recommendation lacked detail, for example, on the number of analytes to be tested

After additional discussion, the committee agreed to a more general recommendation to EPA about completing a follow-up study to confirm the performance of the procedure(s) proposed for promulgation. The committee voted on the recommendation as revised and approved it by consensus.

Additional Recommendation #2
The FACDQ agrees to approve the following Additional Recommendation:
"The FACDQ recommends that EPA's Office of Water complete a follow up pilot study to confirm the performance of the procedure(s) proposed for promulgation."
Vote*: 17 Agree, 3 Not Opposed (*Tom M., Steve B., David K.*), 0 Disagree *(9-19-07)
APPROVED

Uses #4

Alternative 1: 1 Green Dot, 1 Yellow Dot, 1 Red Dot

Alternative 2: 4 Green Dots

Alternative 3: 3 Green Dots, 15 Yellow Dots

Following a break, Mr. Wheeler turned to Uses #4 and reviewed the numbers of dots for each of the alternatives and the written comments. He noted that Alternative 3 had gotten the most responses; Alternative 1 had one red dot and Alternative 2 had only two responses.

Through a quick show of hands, it became clear that there were proponents and opponents of all three alternatives. The committee had a lengthy discussion about what should be included in its recommendation and how to understand the components in various combinations. Mr. LaFleur encouraged the committee to think about how best to set a course of the future rather than focusing on the past. This discussion was interrupted to allow for Public Comment.

Public Comment

At 4:45 pm Richard Reding opened the Public Comment period and noted that Bhupinder S. Dhaliwal, Laboratory Superintendent of Central Contra Costa Sanitary District, had sent a four-page memorandum to EPA with comments critical of the FACDQ Single-Laboratory DL-QL Procedure (Version 2.4). Because Mr. Dhaliwal was not on the line at 4:45 PM, Mr. Reding read the beginning and ending paragraphs of the memorandum.

Key points from the memorandum were that the proposed procedure would "result in millions of dollars in wasted laboratory resources without any additional benefit or improvements in the data quality or the

protection of the environment and human health." In his opinion, there were three critical regulatory issues that a proposed procedure should be able to address: could it identify how much of a pollutant was present; did it produce accurate (rather than precise) results; and could a majority of laboratories measure accurately at a given level using the same analytical methods? In his opinion, the FACDQ procedure failed in all three cases.

By the time Mr. Reding completed reading the final paragraph, Mr. Dhaliwal had been able to call in, to be able to respond to questions. However, the committee had no questions. Since there was no further public comment, Mr. Reding closed the public comment period and the committee reconvened, with a quorum of members still present.

Discussion of Uses #4 (continued)

Issues discussed included how to generate multi-lab data; preferences for QL_{nat}s by analyte or by analyte/method; concerns about stifling approval of new methods in Part 136 if QL_{nat}s were required upon promulgation; and questions about how rigorous and useful a QLmethod would be. A straw poll showed that 14 favored and no one opposed recommending a QL_{nat} by analyte in a Part 122 table. (Part 122 presents non-binding permit requirements; Part 123 presents binding permit requirements.)

The committee took a dinner break at 5:20 pm and reconvened at 6:35 pm.

Mr. Wheeler reported that a subgroup had developed an option for Use #4 (projected before the committee and revised in response to discussions) that consisted of the following points, the last of which had three alternatives:

1. The FACDQ recommends that QL_{nat}s be promulgated in a Part 122 table by analyte.
2. The FACDQ recommends that EPA generate QL_{nat}s as rapidly as possible for analytes with water quality criteria below the capability of existing and/or future methods.
3. Does the FAC recommend that

1. QLmethods be promulgated for future methods using the

FACDQ recommended multi-lab procedure? OR

2. No QLs be incorporated into existing or future methods unless QL was developed using the FACDQ recommended procedure? OR

3. That QLmethods be promulgated for future methods using a procedure other than the FACDQ-recommended procedure?

Zonetta English asked if the committee thought it would end up with an FACDQ-recommended procedure. In response, Mr. LaFleur said he did not think so. The Technical Work Group had developed a recommended procedure and industry had floated an industry-caucus sponsored draft on Target MQO Bounds. Mr. Burrows said that he thought the committee could agree by consensus on a QL_{nat} developed through multiple labs and suggested that the committee consider recommending that EPA develop a national QL based on multiple labs. Mr. Fitzpatrick recommended caution since it was unclear what procedure would be used and Mr. Burrows agreed.

Ms. English asked how realistic it was to expect that EPA would create a QL_{nat} without a process to develop it. Ms. Smith said she did not know if the committee would have a procedure recommendation or not but she said the committee could propose a process for developing a QL_{nat}. She said that EPA currently generated QLs for all analytes for a method. EPA could focus, instead, on the ones it needed most. The committee then explored the ramifications of various choices, numbered 1, 2, 3a, 3b, and 4, which were complicated by the fact that the committee did not yet have a recommended procedure, and continued to search for ways to find areas of agreement. The committee

At the end of the discussion, it was suggested and agreed that the committee would focus on presented voting language options 1, 2 and 3b when it returned to the topic of Uses #4 on Day Two; it would delete options 3a, 3b and 4. The committee then had a lively discussion about the relative merits of continuing to work on Use #4 at the start of the meeting versus beginning work on a procedure recommendation, a critical piece of the committee's charge.

At the end of the discussion, it was decided that the committee would take up the procedure recommendation when it convened on Day Two, beginning with a presentation by Richard Burrows. The committee was expected to vote on a procedure before lunch. The committee would then return to Uses and other issues after lunch. Mr. Wheeler identified a subgroup consisting of Mary Smith, Steve Bonde, John Phillips or Larry LaFleur, Michael Murray, Dave Akers and a member of the Public Utility caucus (not yet identified) to work on language for Use #4.

The meeting adjourned at 7:45 PM.

Day Two – Thursday, September 20, 2007, 9:00 AM – 6:30 PM

Opening and Agenda Review

Richard Reding, EPA Designated Federal Officer (DFO), opened Day Two of the meeting at 9:00 AM, welcomed participants, and indicated that a quorum of members was present. He then turned the meeting over to Bob Wheeler, facilitator.

Mr. Wheeler handed out and reviewed an agenda for the day that reflected decisions made at the close of the meeting on Day One. The committee would focus on a procedure recommendation in the morning, beginning with a presentation on the procedure by Richard Burrows and presentations by John Phillips and Ken Miller on the data and analysis used to develop the procedure. A vote on the procedure would be taken before lunch. After a lunch break, the committee would return to work on other decisions not completed the previous day. He noted that a subgroup consisting of Dave Akers, Steve Bonde, David Kimbrough, Larry LaFleur, and Mary Smith had met at 7:30 that morning to develop language for Use #4. Remaining issues, definitions and the Final Report would be addressed on Day Three (Friday).

FACDQ Single-Lab Detection/Quantitation Limit Procedure

Richard Burrows used a PowerPoint presentation to explain that the DQFAC procedure had been developed from the ACIL procedure, that it was piloted for 5 methods by at least 8 labs per method, and that it had been modified to address shortcomings noted during the pilot study. He described the definitions of Detection and Quantitation that were used in the procedure and walked the committee through the steps in the procedure, including the verification process built into it, and the implications of using "K" rather than the "Student t" factor. He compared the procedure to the factors in the committee's document, "What do we need a procedure to do?" He addressed questions related to cost and ease of operation and compared it to the MDL procedure.

Discussion

Tim Fitzpatrick asked how the procedure dealt with method blank bias, for example, in comparison with the example of 1631 that allows for accounting for method blank bias but in DI water samples that can artificially raise the DL. Mr. LaFleur responded that this got to the issue of blank subtraction which was very complex. Mr. LaFleur asked how the procedure controlled for qualitative identification at the DL. Mr. Burrows responded that, for results above the DL, where a QL is set at the minimum distance above the DL, qualification criteria have to be met. If one spikes at a true concentration, one might not always see it.

John Phillips presented several spreadsheets of data as he explained how a small group had tried to test the procedure by looking at blanks and spikes gathered over several years primarily by the Florida Department of Environmental Protection. Among other findings, this analysis showed that use of the "K" factor produced

many fewer false negative rates while the "Student t" targets an average of 1% false negatives. The group concluded that "K" does a better job than the "Student t" factor in meeting the FACDQ's goal of 1% false positive for uncensored methods.

In the Lowest Expected Result (LER) check for 5% false negative rate, using the "Student t" factor, the vast majority passed whereas using "K", there were more failures, which caused an increase in the QL. He concluded that if "K" were used rather than the "Student t" for censored methods, the QL would be elevated but with no environmental benefit.

Existing Data Analysis, Using Existing Data to Evaluate the FACDQ Single-Lab Procedure

Ken Miller of CSC then gave a PowerPoint presentation to describe the data from Florida Department of Environmental Protection and East Bay Municipal Utility District (MUD) used for the analysis. His presentation addressed what the Procedure Strike Team had looked for and wanted to learn from the data and summarized what they had learned about performance, using both the "Student t" and the "K" factors.

Discussion

Comment: Michael Murray asked what the potential was for lowering the DL. He expressed concern that the focus seemed to be on not letting the DL and QL go down. For him, it came back to the issue of blank contamination and taking measures to address that, which raised the DL, which could also raise the QL.

Response: Richard Burrows said that the DL could be adjusted up or down whenever one did a reassessment. With respect to control of blank contamination, he said there was nothing in the procedure that required action at any point. That was because they were trying to determine a DL. Once you have a DL, he said, you may decide that you do or do not have the right method for the purpose. He added that use of data would require going up or down, to meet customer needs. With respect to LER, he said a consequence of LER failure would be to raise the QL. The worse the performance, the more the QL would be raised.

Comment: Steve Bonde said he echoed Dick Reding's concerns about less than zero average values one could get from an uncensored set of data. Could the committee recommend that labs address the calibration of their instrumentation using the weighted linear regression?

Response: Mr. Burrows said that one could not solve everything with the DL procedure.

Question: Mr. Fitzpatrick asked about the optional batch verification procedure. He noted that if a method had performance requirements for accuracy, one could measure batch-by-batch, but without long-term data, he asked how one could verify and report precision? How would you treat accuracy

and precision if they were required?

Response: Mr. Burrows said that all the lab would have would be the results of the first seven replicates. The lab might have to use a different method to get what Mr. Fitzpatrick was interested in.

Response: Mr. Phillips said, in response to Mr. Fitzpatrick's question, that there was an optional batch verification procedure. If there were precision and accuracy specifications in the method, they would be average recovery values. With batch-by-batch verification, if you stayed within the average recovery value, you could probably stay within the precision.

Response: Mr. LaFleur said that it would depend on the recovery criteria which might not be a given.

DL/QL Procedure Recommendation

The committee developed revised language for the procedure recommendation. Mr. Wheeler proposed a straw poll on the revised version of the procedure recommendation to see where the committee was on that version. The committee took a straw poll but failed to reach consensus.

Lab-Determined Detection Limits and Quantitation Limits (*As Is*)
The FACDQ recommends that EPA promulgate the DQFAC Single Laboratory Procedure v2.4 recommended by the FACDQ for individual laboratories to determine their detection and quantitation limits. The DQFAC Single Laboratory Procedure v2.4 shall be used instead of the current MDL procedure in 40 CFR Part 136, Appendix B, for calculating all future Laboratory Detection and Quantitation Limits. The DQFAC Single Laboratory Procedure v2.4 has the following two capabilities:

- Demonstrates the lab's performance at a specified level.
- Determines the lowest possible value achievable by the lab while meeting the measurement quality objectives (MQOs).

***Straw Vote*: 9 Agree, 8 Not Opposed, 3 Disagree,** *(9/20/07)*

The committee then discussed the opportunity to revise the above proposal and then vote on modifications to the recommendation. Mr. Wheeler conducted a straw poll on whether or not the committee wanted to take time to make these modifications. The committee

took a straw poll but failed to reach consensus.

Lab-Determined Detection Limits and Quantitation Limits (*With Quick Resolution on Modifications*)

*Note: This vote reflects the Committee's desire to explore potential modifications and spend time on the language below:

The FACDQ recommends that EPA promulgate the DQFAC Single Laboratory Procedure v2.4 recommended by the FACDQ for individual laboratories to determine their detection and quantitation limits. The DQFAC Single Laboratory Procedure v2.4 shall be used instead of the current MDL procedure in 40 CFR Part 136, Appendix B, for calculating all future Laboratory Detection and Quantitation Limits. The DQFAC Single Laboratory Procedure v2.4 has the following two capabilities:

- Demonstrates the lab's performance at a specified level.
- Determines the lowest possible value achievable by the lab while meeting the measurement quality objectives (MQOs).

***Straw Vote*: 10 Agree, 8 Not Opposed, 2 Disagree** *(9/20/07)*

The committee took a break and reconvened at 11 AM.

Mr. Wheeler asked the committee if it wanted to address an optional batch verification recommendation proposed by David Kimbrough and a recommendation on QL Verification Frequency, proposed by the industry caucus. The committee agreed.

Discussion of the Optional Batch-by-Batch Verification

Comment: Ms. Thomey volunteered the perspective of a small commercial lab because, she said, small lab issues were often raised. She acknowledged that there was always a learning curve with something new which could seem burdensome. However, she said, if EPA followed through with a guidance document and an on-line calculator, those tools would minimize the burden. She did not see this procedure as more burdensome than the current procedure.

Question: Mr. Mugan asked how one developed an initial DL if there were no estimate of false positive/false negative rates. If a blank were way below a DL, what did the lab do?

Response: Mr. Burrows said that the lab would continue with the new DL unless and until the lab decided the performance was such that it could start over with seven replicates.

Comment: Mr. Fitzpatrick said that intermittent contamination was an ongoing problem that could affect batch-by-batch verification.

Comment: David Kimbrough reported that about 400 Clean Water Act labs had met at the most recent California Lab Accreditation meeting earlier in the year where a lot of concern was expressed about the requirements of the procedure. He said that many of the labs are very small (one to two people) and that they would never collect enough blanks for verification. They also lack LIMS systems. He said for a lot of these labs, this procedure would be a lot of extra work.

Comment: Mr. Fitzpatrick said he understood but if precision were required, there were no steps around it.

Response: Mr. Burrows agreed with Mr. Fitzpatrick.

Comment: Mr. Cary agreed that Mr. Kimbrough's report was representative of municipal labs across the county and he expected to get comments similar to those from the Contra Costa Lab read during the public comment period during rulemaking. It tended to increase DLs, not decrease them.

Comment: Ms. Smith said she wanted to make a statement. With respect to the procedure, she said that EPA was a red dot. While there were lots of things about the new procedure the agency liked and could support, there were two things that remained concerns: use of "Student t" vs. "K" and controlling for false negatives, the end result of which was to raise the QL. After going through the confirmatory study, she said, perhaps EPA would feel more comfortable with the procedure. What EPA was seeing, she said, was that DLs/QLs were going up relative to the MDL results.

Response: Mr. Burrows said that during the pilot study, "K" was used for everything. In Version 2.4 the "Student t" is used for some things. The doubling of QL with "K" was only a significant factor when only seven replicates were available; the impact of using "K" decreases with higher numbers of replicates. With respect to controlling blanks, he said, if we are serious about DQOs, then labs have to generate data that meet DQO needs that are below the QL_{per}. If a lab's QL is lower than the QL permit, there is no reason to go lower than needed. He cited the example of mercury. If a lab needed to generate data with accuracy results at 1 to 2 ppb, then blanks were not good enough but if the need was for 100 ppb, then blanks were completely adequate.

Question: Mr. Fitzpatrick said he understood EPA's concerns about using false negatives to control QLs but asked how one could define QL if not through accuracy, precision or false negative rates.

Comment: Mr. Reding said that false negatives were not protective of the environment; he added that precision and accuracy were still part of the calculation of QL.

Suggestion: Mr. Phillips suggested adding a new bullet point under Optional Batch Verification: If the QL spike result was outside the average specified accuracy, elevate the QL by a factor of two and repeat the QL spike.

Comment: Mr. Kimbrough asked where accuracy and precision fit in the calculation since we don't have them.

Response: Mr. Reding said if those benchmarks were available, they should be put in.

Comment: Mr. LaFleur said that the procedure now stated you had to have accuracy and precision.

Comment: Mr. Fitzpatrick said he did not see how to avoid a false negative (as well as a false positive) rate since the committee had voted on it earlier.

QL Verification Frequency

John Phillips said that the procedure specifies a monthly frequency with quarterly evaluation. The industry caucus would like monthly QL evaluation spikes, evaluated annually. He said the DL verification recalculation was specified for an annual test but the revised procedure allows for recalculation of the DL. Minor modifications to the verification process, he said, would address their concerns.

Discussion

Comment: Richard Burrows asked Mr. Reding if EPA intended to generate accuracy and precision criteria for all methods in Part 136 because, until then, the only basis for QLs would be the false negative rate. With respect to spiking frequency, he said to John Phillips, that they had tried to keep cost of the new procedure at the level of the current MDL. If monthly spike checks would be required, it would be hard to keep costs affordable.

Comment: Mr. Murray said he remained concerned about low WQBEL situations. He asked Mary Smith if there would be scientific peer review of the procedure before promulgation.

Response: Ms. Smith indicated that EPA would conduct peer review and it was possible it would conduct peer review in parallel with rulemaking, before the process was finalized.

Comment: Mr. Akers said that he understood the need to accommodate small labs but he thought the goal was to have predictability of results, rigor and understandings on the use of the data gathered.

Response: Mr. Burrows said that what had been done with batch-by-batch verification was to make adjustment of the DL/QL quite stringent. As a result, he expected that DLs/QLs would be quite similar regardless of whether long-term monitoring or batch-by-batch processes were used. He said the goal was to have a procedure that worked for everyone. With respect to recalculation of DLs every year, he said that a lot of data users did not want their data to flip around.

Comment: In regard to a monthly frequency, Mr. Kimbrough said that all labs did a run each month. The tradeoff was that labs using the batch-by-batch process would have more stringent results.

Comment: In the way of a general response to Mr. Murray's concerns, Mr. Burrows said that there was a procedure and a method and the procedure told us how to perform the method. He said he was not in favor of fancy statistical gyrations; instead, there was a need to do a better job of the method in the labs.

Comment: Mr. Murray acknowledged that the procedure and the method were related. He said he did not want a procedure that did not encourage dealing with blank contamination in the method.

Comment: Mr. Avery noted that Mr. Fitzpatrick had raised the issue that the procedure would not work with methods that provided for blank correction.

Response: Mr. Burrows agreed that if blank contamination came from something not added to the samples, it would bias the results upwards.

Comment: Mr. Fitzpatrick said that it was hard to account for that situation but he also felt it wasn't insurmountable.

Question: Ms. English asked where these options had come from and if the committee would vote on them.

Response: Mr. Wheeler said that the committee would vote on the former Use #1 (now the procedure recommendation) with the comments removed.

Question: Mr. Fitzpatrick asked which version of the procedure the committee would vote on.

Response: Mr. Wheeler said it would be version 2.4 document (13) DQFAC Single Lab DL-QL Procedure Version 2.4, with a correction from 20 to 30, revision of the second footnote and deletion of the third footnote.

Comment: Ms. Smith asked that the footnote about the necessity of public comment be inserted in the Final Report the first time "promulgation" came up in the Report.

To assess where the committee was, Mr. Wheeler conducted a brief straw poll on the procedure recommendation. The results showed 17 members agreed or were not opposed to the recommendation but three members were opposed.

The committee broke for lunch at 12:25 pm and reconvened at 1:30 pm to continue voting.

Removal of Recommendations #1-#3 from the Uses Document

The first vote of the day was on a proposal to remove recommendations #1-3 from the Uses document. The committee approved the recommendation by consensus.

Moving Use #1-#3 from the Uses Document
The FACDQ agrees to remove Uses #1-#3 from the Uses Document.
***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-20-07)*
APPROVED

ICIS Language

The committee then discussed particular language throughout the document that referred to updates of 40 CFR QL_{nat}s and the ICIS system and voted on removing it.

ICIS Language
The FACDQ agrees to remove the following language from two places in Use #5 in the Uses Document:
"for purposes of updating 40 CFR Part 136 National Quantitation Limits."
Vote*: 16 Agree (Dave A., Bob A., Tim F., Tom M., Steve B., Richard B., Nan T., Roger C., Larry L., John P., Dave P., David K., Michael M., Rick R., Barry S., Mary S.*)**, 3 Not Opposed (***Cary J., Chris H., Jim P.*)**, 0 Disagree, 1 Absent (***Zonetta E.*) *(9-20-07)*
APPROVED

Formal Peer Review of the Procedure

The committee then turned to the proposal for a formal scientific peer review process for the procedure. Ms. Smith clarified that the agency would conduct a formal review process in any case if a majority of the committee voted in favor of the procedure. In response to questions, she said she would not typically prepare a formal Federal Register notice or request public comment for a formal review. After discussion and some rewording of the recommendation, the committee voted and approved the following recommendation by consensus.

Peer Review of the Procedure
The FACDQ recommends that a formal peer review take place for the FACDQ recommended procedure.
Vote*: 16 Agree, 4 Not Opposed (Bob A., Nan T., Zonetta E., Jim P.*)**, 0 Disagree** *(9-20-07)*
APPROVED

Batch-Specific Verification

In committee discussion, members asked about the consistency of the proposed batch-specific verification with the committee's definitions of detection and quantitation. Concern was also expressed that it would uniformly increase DLs. The committee voted on the recommendation but failed to reach consensus.

Optional Batch Specific Verification

The FACDQ recommends that the following language be moved into the DQFAC Single Lab Procedure v2.4:

Blanks and QL spikes in each batch

a. If the method blank exceeds the DL and a cause cannot be identified, raise the DL to the blank result for future analysis
b. If the QL spike result (or QL spike times QL/spike level, if not spiking exactly at the QL) is less than the DL, elevate the QL by a factor of two and repeat the QL spike at the new QL. Repeat this until the QL spike is at or above the DL.
c. If the QL spike result is outside the average specified accuracy, elevate the QL by a factor of two and repeat the QL spike at the new QL. Repeat this until the QL spike meets the specified accuracy criteria

Vote*: 4 Agree (*Zonetta E., Chris H., Jim P., David K.*), 9 Not Opposed (*Richard B., Cary J., Nan T., Roger C., Larry L., John P., Dave P., Rick R., Barry S.*), 7 Disagree (*Dave A., Bob A., Tim F., Tom M., Steve B., Michael M., Mary S.*) *(9-20-07)

NOT APPROVED

In discussions following the vote on batch-specific verification, Mr. Fitzpatrick suggested that the committee should, nonetheless, put forth a direction to EPA and ask that EPA be tasked with developing that direction. In response, Ms. Smith noted that the committee had only one more meeting and thus would have no opportunity to consider and vote on a proposal. She agreed that the Technical Work Group could work on this issue, give a report to the committee in December, and have their results included in the Appendix to the Final Report.

The committee finalized the language to be voted on, as follows:

Batch Verification
The FACDQ recommends that during promulgation, EPA include and/or develop language to incorporate batch specific verification as an option in the procedure.
***Vote*: 16 Agree, 4 Not Opposed** (*Tom M., Richard B., Cary J., Mary S*), **0 Disagree** *(9-20-07)*

APPROVED

QL Verification Frequency

The committee considered a proposal to incorporate language on the frequency of QL verification in the procedure itself. The committee voted on the proposal but failed to reach consensus. The red highlighted language in the recommendation below is the language the committee agreed to add into the recommendation before voting.

QL Verification Frequency

The FACDQ recommends that the following be adopted into the DQFAC Single Lab Procedure v2.4:

Section 2.10 of the ACIL procedure specifies monthly QL verification spikes, evaluated on a quarterly basis. Section 2.2 of revised ACIL procedure specifies a minimum of quarterly QL verification spikes, evaluated on an annual basis. If we went to monthly QL verification spikes, evaluated annually this would provide a minimum of 24 QL spikes over a two year period to generate the long term estimate:

> 2.2 Continue to collect method blanks with each batch from which data were reported and QL spikes for every analyte analyzed at least monthly (or four per twelve month period in separate batches spread across the time period during which analysis is conducted) which ever is greater. If multiple instruments are to be used for reporting data with the same DL and QL, analyze two to six QL spikes per instrument per twelve month period, so that a minimum of twelve QL spikes are generated each year.
>
> 2.2.1. Evaluate your DLs and QLs at least every year using all of the spikes available in a 24 month period using the procedures described in the Sections below. All method blanks and QL spikes collected within a 24 month period should be used for reassessing DLs and QLs, unless there is reason to believe that the DL or QL changed substantially at some point during that 24 month period. In that case the most recent data may be used for the reassessment, but not less than 20 method blanks and seven QL spikes per instrument.

[1]For multi component analytes a lab may use representative analytes to collect data for classes of compounds. When a representative analyte is monitored, the other analytes that compound represents must have similar sensitivity and method performance characteristics as demonstrated in initial DL/QL studies. If DLs or QLs for a monitored analyte are adjusted, as a consequence of on-going verification, the same adjustment must be applied to all analytes represented. An example is method 608 which includes several Aroclors, Toxaphene, and technical Chlordane. In this case, a mixture of Aroclors 1016 and 1260 might be used to represent all Aroclos. Toxaphene may be used to represent both Toxaphene and technical Chlordane.

Vote*: 4 Agree (*Roger C., Larry L., John P., Dave P.*), 5 Not Opposed (*Zonetta E., Chris H., David K., Jim P., Rick R.*), 11 Disagree (*Dave A., Bob A., Tim F., Tom M., Steve B., Richard B., Cary J., Nan T., Michael M., Barry S., Mary S.*) *(9-20-07)

NOT APPROVED

Mr. LaFleur then proposed the revised language as follows that the committee then voted and approved.

QL Verification Frequency
The FACDQ recommends that EPA give additional consideration to increasing the frequency of QL verification and report its findings in the preamble of the Federal Register Notice and request specific comments on the final proposed frequency.
***Vote*: 11 Agree, 9 Not Opposed** (*Bob A., Tim F., Tom M., Steve B., Richard B., Cary J., Nan T., Michael M., Mary S.*) **0 Disagree** *(9-20-07)*
APPROVED

Recalculate the DL

Mr. Phillips pointed out that if one did not recalculate the DL, it would not be reset at the 1% false positive rate, resulting in higher false positive rates. The recalculation would adjust it up or down. Mr. LaFleur added that, without recalculation, one would always be using short-term data. The committee voted on the proposal but failed to reach consensus.

DL Verification and Recalculation
The FACDQ recommends that the following be adopted into the DQFAC Single Lab Procedure v2.4:
Section 1.9 of the ACIL procedure specifies annual recalculation of DL and then uses an F test to determine if the DL should be revised. Section 2.2.2 (now 2.4) allows optional recalculation of the DL, with no decision criteria provided. By making the recalculation of the DL optional it is possible that the false positive error rate using the parametric statistical test could be greater than 1%.

> 2.2.2 Recalculate the DL using the formulas in 1.1.7. or 1.2.7.
>
> ***Vote*: 8 Agree** (*Dave A., Roger C., Larry L., John P., Dave P., Zonetta E., David K., Jim P.*), **10 Not Opposed** (*Bob A., Tom M., Steve B., Richard B., Cary J., Nan T., Chris H., Michael M., Rick R., Barry S.*), **2 Disagree** (*Tim F., Mary S.*) *(9-20-07)*
> **NOT APPROVED**

Later in the meeting, the committee identified the following authors for majority/minority reports on recalculating the DL:

Majority Team: David Kimbrough, Larry LaFleur, Mary Smith

Minority Team: Tim Fitzpatrick and Mary Smith

The committee did not provide points for the majority/minority rationales.

DQFAC Procedure Recommendation

Mr. Burrows corrected a typo on p. 8 of the procedure, section 4, last paragraph below #1 and #2, by replacing "above" with "below." Mr. Wheeler reminded the committee that the number 20 in the procedure (p. 5 and 7) should read 30 for consistency.

The committee voted on the procedure recommendation but failed to reach consensus.

Lab-Determined Detection Limits and Quantitation Limits

The FACDQ recommends that EPA promulgate[1] the DQFAC Single Laboratory Procedure v2.4[2] recommended by the FACDQ for individual laboratories to determine their detection and quantitation limits. The DQFAC Single Laboratory Procedure v2.4 shall be used instead of the current MDL procedure in 40 CFR Part 136, Appendix B, for calculating all future Laboratory Detection and Quantitation Limits. The DQFAC Single Laboratory Procedure v2.4 has the following two capabilities:

- Demonstrates the lab's performance at a specified level.
- Determines the lowest possible value achievable by the lab while meeting the measurement quality objectives (MQOs).

***Vote*: 14 Agree (*Dave A., Bob A., Tim F., Tom M., Steve B., Richard B., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Jim P., Rick R.*), 1 Not Opposed (*Chris H.*), 5 Disagree (*Cary J., David K., Michael M., Barry S., Mary S.*)** *(9-20-07)*

NOT APPROVED

Following the vote, Mr. Reding acknowledged the tremendous work the Technical Work Group had put into the development of the procedure and said he felt a lot of progress had been made.

The committee then assigned Richard Burrows, John Phillips and Tim Fitzpatrick to write the majority report and Cary Jackson, David Kimbrough, Michael Murray, Mary Smith to write the minority report.

Majority Rationales

- Positive remarks from Richard Burrow's PowerPoint presentation on the single-lab procedure, including comparisons with the MDL
- To include: rationale for why the majority did not favor more frequent QL verification
- Reporting

Minority Rationales

- Excessive overhead for most CWA labs
- Similarities to the current MDL
- Use of "Student t" factor vs. "K"
- Potential excessive protection of False Negatives over False Positives
- False negative corrective factor
- Uncontrolled reagent blanks
- Need for more frequent QL verification (that the FACDQ did not support in the earlier vote).

After the procedure vote, the committee identified several procedural questions. These questions are presented with the Final Report discussion on Day 3.

After a break, the committee reconvened at 3:15 PM and Mr. Reding noted that a quorum was present.

Additional Recommendation #5 (15 Green Dots, 2 Yellow Dots, 1 Red Dot)

Jim Pletl briefly presented the recommendation. Barry Sulkin stated that it should be clear that the committee made a conscious decision not to address 303(d) issues. Ms. Smith said that EPA had voted "red" on this recommendation (as well as #6) because she felt if she had voted "green," she was committing EPA to do the work it identified. Given other commitments already made (developing guidance documents, drafting a

Federal Register notice, etc.), she said her management did not want to commit to more work.

Mr. LaFleur responded that the recommendation included no timeline; he said that some of the committee would be happy if the agency were to take it up within the next five years. Mr. Pletl said it made sense for EPA to look at its resources and to prioritize what to take up next.

Mr. Fitzpatrick asked what the differences were between #5 and #6. Mr. Pletl responded that #6 addressed expectations about the DQO process and confirmed that the FACDQ expected that DQIs and MQOs would be generated. He said he wanted to be sure there was a common understanding about the implications of following DQO guidance. The committee voted on the recommendation but did not reach consensus.

Additional Recommendation #5
The FACDQ agrees to approve the following Additional Recommendation:
"EPA evaluate and modify the uses of data in CWA programs (beyond those uses discussed in the FACDQ recommendations) based on data uncertainty and decision error rate requirements relative to corresponding detection and quantitation limits. This could be accomplished through establishment of and adherence to data quality objectives for all CWA programs. How data relative to detection and quantitation limits are to be used in 303(d) listings, reasonable potential determinations, NPDES effluent limit derivation, the development of water quality criteria, and other uses should be documented."
Vote*: 13 Agree (*Dave A., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Michael M., Rick R., Barry S.*), 6 Not Opposed (*Bob A., Tim F., Tom M., Steve B., Richard B., Cary J.*), 1 Disagree (*Mary S.*) *(9-20-07)
NOT APPROVED

After the vote, Jim Pletl was assigned to write the majority report and Mary Smith was assigned to write the minority report. Points to be made in the minority report were inconsistencies in the recommendations and the fact that EPA could not commit the time and resources required at this time.

Additional Recommendation #6 (16 Green Dots, 2 Yellow Dots, 1 Red Dot)

In the brief discussion before the vote, Mr. Pletl clarified that the intent was not to tell the agency what DQOs or MQOs to adopt or if it should adopt a single set of MQOs for all analytes across programs. That was left intentionally vague. Mr. Jackson said that he was not opposed to the recommendation but thought it

could not be implemented given the massive work involved in permit writing. The committee voted on the recommendation but failed to reach consensus.

Additional Recommendation #6
The FACDQ agrees to approve the following Additional Recommendation:
"EPA establish data quality objectives (with indicators and measurement quality objectives) for CWA programs where detection/quantitation limits are used in decision making."
Vote*: 15 Agree (*Dave A., Bob A., Tim F., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Michael M., Rick R., Barry S.*), 4 Not Opposed (*Tom M., Steve B., Richard B., Cary J.*), 1 Disagree (*Mary S.*) *(9-20-07)
NOT APPROVED

After the vote, Jim Pletl was assigned to write the majority report and Mary Smith was assigned to write the minority report. The committee did not identify key points for the majority or minority rationales.

Uses #4 (Revised language prepared by the 7:30 AM Work Group)

In response to a question, Mr. Wheeler explained that the revised language was intended to replace the three alternatives presented and discussed on Day One. Mr. LaFleur clarified that how QL_{nat}s would be determined would not be in the Uses section.

The committee had a significant and lengthy discussion about the data to be collected, the purposes for collecting it, and expectations for reporting and using data in EPA's ICIS database. With respect to use of the data, Mr. LaFleur said that industry was concerned that it would do a lot of work to collect and report the data, and it did not want to vote for this process until it was clear how the data would be used. Ms. Smith added that EPA, like industry, saw this as an important issue but the proposal had come in late the preceding Friday; the Technical Work Group had not had time to develop a consensus proposal, and she did not want to rush to judgment. She said it was difficult to understand the details and the resource ramifications quickly.

Dave Akers pointed out that some of the data in the database would be important for compliance decisions and for establishing QLnats. He noted that for states regulating analytes with WQBELs, it would be important to have a database with that information. Mr. Fitzpatrick added that the Director of Florida's wastewater program pointed out that data for wastewater are often used for other purposes and it was useful to see the DL relative to the data. Mr. LaFleur said that was why the Uses document allowed for requesting

that information but separately from the DMR. He recalled that the committee had come up with QL_{nat} based on ICIS because Uses said that data would be collected and used for that purpose. After discussion, committee members agreed it made sense to recommend a more general approach and to delete the provision for reporting data to the ICIS database.

A straw poll on revised language was taken.

Promulgation of QL_{nat}

The FACDQ recommends that EPA promulgate a QL_{nat} with the following minimum requirements:

a. EPA will use the DQO process to set target MQOs for NPDES permit compliance testing.
b. A minimum of 6-7 labs.
c. Data collected at a minimum over 3- 6 months.
d. A minimum of 20 QL spikes used in the calculation of each single lab limit.
e. The data and lab be evaluated for validity prior to acceptance.
f. An appropriate outlier test is then applied to the dataset.
g. Evaluate the data for normality, using standard statistical tests.
h. If the data is normally distributed then calculate the upper 95% confidence limit, which becomes the QL_{nat}.
i. If the data is non-normally distributed then the 95th percentile QL_{lab} becomes the QL_{nat}.
j. EPA should then promulgate the newly calculated QL_{nat}.

***Straw Vote*: 8 Agree, 10 Not Opposed, 1 Disagree, 1 Abstain** *(9-20-07)*

After the straw vote, the committee continued to discuss options for reaching agreement. Those discussions were interrupted to allow for the scheduled Public Comment period.

Public Comment

Mr. Reding opened the public comment period at 4:45 PM. Shen-Yi Yang of EPA's Office of Solid Waste commented on the procedure the committee had proposed. She said the Office of Solid Waste felt that the procedure pushed the DL and QL too low. She noted that the committee and the Office of Solid Waste used different definitions of Detection. She said that the committee' definition of Quantitation was similar to Solid Waste's definition of Detection. She noted that Solid Waste often received results with high matrix

interference. The Office, she said, is skeptical that labs can see the detects they claim. The Office of Solid Waste would like to see the Technical Work Group review a lot of datasets and see if the Group can see the signal to noise ratio at 5 to 1. She said that Solid Waste had performed this procedure and could not see a result. She said that Solid Waste was glad that the procedure provides verification. She said she did not think verification would be a burden.

As there was no other public comment, Mr. Reding closed the public comment period and the committee meeting resumed, with a quorum of members present.

Use #4 Discussion (Continued)

The committee continued to revise the language, projected on a screen before the group, to address a variety of questions and concerns. After the committee finalized the language for Uses #4 to reflect the discussion, the committee voted on the recommendation and reached consensus.

Promulgation of QL_{nat}s for Existing and Future Methods (Formerly Use #4)

The FACDQ recommends that:

a. QL_{nat}'s be promulgated in a Part 122 table by analyte
b. EPA generate QL_{nat}s as rapidly as possible so that recommendation #TBD (current section 5 of the Uses Document) can be fully implemented.
c. QL's be promulgated only using the nationally promulgated approach.
d. Methods may be promulgated without promulgating a QL for that method. As new methods are proposed without a promulgated QL, data (eg: Single Lab Detection, Single Lab Quantitation, etc.) showing demonstrated method performance should be included in the method. The methods should include a statement that these performance levels are guidance and may not always be achievable.

***Vote*: 16 Agree, 4 Not Opposed** (*Cary J., Nan T., Zonetta E., Chris H.*), **0 Disagree** *(9-20-07)*

APPROVED

Promulgation of QLs

The committee discussed differences and how to distinguish among the various types of QLs, including a QL, a QL_{nat}, and a QLmethod. The committee voted on final language and did not reach consensus.

Promulgation of QLs

The FACDQ recommends the following criteria be considered when EPA proposes the procedure for determining a QL:

a. EPA will use the DQO process to set MQO target MQOs for NPDES permit compliance testing.
b. A minimum of 6-7 labs.
c. Data collected at a minimum over 3- 6 months.
d. A minimum of 20 QL spikes used in the calculation of each QL_{lab}.
e. The data and lab be evaluated for validity prior to acceptance.
f. An appropriate outlier test is then applied to the dataset.
g. Evaluate the data for normality, using standard statistical tests.
h. If the data is normally distributed then calculate the upper 95% confidence limit, which becomes the QL.
i. If the data are non-normally distributed then the 95^{th} percentile QL_{lab} becomes the QL.

Vote*: 9 Agree (*Tom M., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P.*), 8 Not Opposed (*Dave A., Bob A., Steve B., Richard B., Cary J., Nan T., Michael M., Rick R.*), 1 Disagree (*Mary S.*), 2 Absent (*Tim F., Barry S.*) *(9-20-07)

NOT APPROVED

After the vote, the committee did not identify an author for the majority report; Mary Smith was assigned to write the minority report. Points to be made in the minority report were the fact that there was a lot of specificity here, not criteria, and it could have a big impact on EPA resources; the agency needed time to think it through

Mr. Wheeler congratulated the committee on its accomplishments. He said that Friday's agenda would focus on the issues not yet finalized as well as on definitions of detection and quantitation and on the Final Report. It was agreed that the Final Report Work Group would convene in the meeting room at 7:15 AM on Friday morning.

Mr. Reding closed the meeting at 6 PM.

Day Three – Friday, September 20, 2007, 8:00 AM – 3:00 PM

Opening and Agenda Review

Richard Reding, EPA Designated Federal Officer (DFO), opened Day Three of the meeting at 8:00 AM, welcomed participants, and indicated that a quorum of members was present. He confirmed that two members had to leave before 3 PM: Mr. Sulkin by 1 PM and Mr. Pletl by 2:30 PM. He then turned the meeting over to Bob Wheeler, facilitator.

Mr. Wheeler proposed that the committee finalize decisions no later than 1 PM in light of the fact that two members would have to leave by then. He said the agenda items for the day included finalizing recommendations related to the following: Target MQO Bounds, Use #5 (Setting Permit Conditions), Verification, Implementation, and Definitions. He also reported that the Final Report Work Group had met at 7:15 AM and wanted Committee discussion and approval of the approach, schedule, and expectations for the drafting the Final Report so the committee would have a good product to review and approve at the December meeting.

Target MQO Bounds

Mr. Phillips said he realized from the committee's earlier discussion that some on the committee wanted to set Target MQO Bounds and some did not. He requested that the committee vote on the issue and identify who would prepare the majority/minority reports.

Committee members asked if the proposal was intended to apply to all of Part 136; if it would have implications for how data were reported or become reportable, and how broadly it would apply (to EPA and to non-EPA methods). A concern was expressed that the proposal was too prescriptive.

The committee voted on the proposal, as revised, but did not reach consensus.

Target MQO Bounds Recommendation

The FACDQ recommends that a single set of MQO bounds be established for promulgated Part 136 methods that define Quantitation for CWA compliance and enforcement uses.

Vote*: 7 Agree (*Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P.*), 3 Not Opposed (*Dave A., Bob A., Tim F.*), 8 Disagree (*Tom M., Steve B., Cary J., Nan T., Michael M., Rick R., Barry S., Mary S.*), 2 Absent (*Roger C., Richard B.*) *(9-21-07)

NOT APPROVED

The committee assigned John Phillips and David Kimbrough to write the majority report and Mary Smith and Nan Thomey to write the minority reports. Key points for the reports were as follows:

Majority Rationales

- It makes common sense
- If can't detect, you can't quantify
- If you can't detect, how can you enforce?
- It makes sense to have minimum criteria to define what quantitation means.

Minority Rationales

- A single set of issues would be too wide
- An objective gives you room for interpretation and I think we should have that
- I'm concerned the bounds could be too narrow, for example, you may need to measure at a level that current methods cannot achieve
- This is anti the spirit of the CWA. We need bounds that are protective of the environment
- A single set is an issue. We have other ways to monitor data points (rather than using a single data point) to determine if a permittee is in compliance.

Use #5 – Setting Permit Conditions (10 Green Dots, 9 Yellow Dots, 1 Red Dot)

The committee first reviewed the dots and written comments on the worksheet for this recommendation and then proceeded to a lengthy discussion about numerous aspects of the recommendation. Issues included the length of the life of the permit, the use of zero for averaging, whether the data reporting should be restricted to cases when WQBELs are below existing capabilities of methods or if they should extend to those above WQBELS. Because of changes that occurred as a result of drafting for the Final Report and decisions on other recommendations (such as removal of reporting in ICIS), there was a concern that some aspects of the recommendation had been lost or no longer fit well together.

As the discussions proceeded, revisions to the recommendation were projected before the committee and discussed. After the language was finalized, the committee took a caucus break to review the recommendation. The language was finalized as follows:

Use #5 Setting Permit Conditions, Reporting and Using Data, and Determining Compliance When the Water Quality Based Effluent Limit (WQBEL) is Less Then Detection and Quantitation Capabilities of Existing Methods

The FACDQ recommends that EPA implement Section #5 of the Uses Document as follows:

Recommendation: The FACDQ recommends that the following recommendations be incorporated into 40 CFR Part 122, as appropriate.

A. Recommendations for NPDES Permit and Compliance Uses When a National Quantitation Limit Exists

If the permitting authority requires use of a method more sensitive than the method for which a QL_{nat} exists, go to section B.

2. **Permit Requirements Related to Detection and Quantitation**

Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 122:

1. The default quantitation limit to be included in the permit or in rule as appropriate (Permit Quantitation Limit) is the Part 122 promulgated National Quantitation Limit unless the regulator

determines that the Permit Quantitation Limit should be adjusted to account for sensitivity, selectivity, and/or matrix effects;

2. The permit shall contain a condition that the quantitation limit determined by the permittee's laboratory (Laboratory Quantitation Limit) shall be at or below the Permit Quantitation Limit. The permittee's laboratory may use any Part 136 method for which they can demonstrate a Laboratory Quantitation Limit at or below the Permit Quantitation Limit. If matrix effects have been given special attention in the permit then they would also have to be considered in compliance and enforcement.

3. The permit shall require the permittee to report the detection limit (Laboratory Detection Limit) and the Laboratory Quantitation Limit and maintain such information for a period of at least five years;

4. The permit shall require the permittee to maintain individual numeric results for a period of at least five years. The regulator may require the individual numeric result for any value that is greater than or equal to the Laboratory Detection Limit and less than the Permit Quantitation Limit be reported in a supplemental report.

5. The permit shall require that the Laboratory Detection Limit and the Laboratory Quantitation Limit be determined using the steps of the 40 CFR Part 136 procedure to establish the lowest possible value by the laboratory;

6. That EPA require the Laboratory Detection Limit, the Laboratory Quantitation Limit, and the Permit Quantitation Limit be reported by the regulator to the Integrated Compliance Information System (ICIS).

3. **Establishing Compliance Thresholds and Determining Compliance**

Recommendation: The FACDQ recommends the following be required where EPA has

promulgated a National Quantitation Limit in 40 CFR Part 122:

1. Regulators will set average and daily maximum permit limits at the WQBEL.

2. Permittees must report to the regulator all information in the following manner on the Discharge Monitoring Report (DMR):

    i. To report daily maximum sample results:

    i. For values not detected at the Laboratory Detection Limit, report "not detected".

    ii. For values detected at the Laboratory Detection Limit but less than the Permit Quantitation Limit, report "detected less than the Permit Quantitation Limit".

    iii. For values greater than or equal to the Permit Quantitation Limit, report the actual numeric values.

    i. To report average sample results:

5. When all values used to calculate an average are not detected at the Laboratory Detection Limit, report "not detected".

6. When all values used to calculate an average are "detected less than Permit Quantitation Limit," report "detected less than the Permit Quantitation Limit."

7. When values used to calculate an average are a combination of "not detected" and "detected less than the Permit Quantitation Limit", report "detected less than the Permit Quantitation Limit".

8. When any value used to calculate an average is greater than or equal to the Permit Quantitation Limit, report the calculated numeric average after assigning zero to any individual value reported either as "not detected" or "detected less than the Permit Quantitation Limit."

    3. To determine NPDES permit compliance with results reported on the DMR, regulators will:

        i. Determine that any daily maximum or monthly average results reported as either "not detected" or "detected less than the Permit Quantitation Limit" are in compliance with the effluent limitation.

        ii. Compare any numeric results directly to the WQBEL

4. **Additional Permit Requirements**

Recommendation: The FACDQ recommends the following be required where EPA has promulgated a National Quantitation Limit in 40 CFR Part 122: Permits shall include language that triggers additional steps when a "significant number" (to be determined in permitting process) of values detected at the Laboratory Detection Limit but less than the Permit Quantitation Limit are reported. These steps may include additional or accelerated monitoring, analytical studies such as matrix studies, pollutant minimization programs, or other permit conditions outside of the determination of compliance with effluent limitations. Reports under such provisions will be done outside of the DMR process, except that any additional effluent testing performed using approved analytical methods as part of the special studies must be reported on the DMR.

B. Recommendations for NPDES Permits and Compliance Uses When No National Quantitation Limit Exists, or if the Permitting Authority Requires a Permit Quantitation Limit lower than the National Quantitation Limit.

Recommendations:

4. In the absence of a National Quantitation Limit, the permitting authority is free to establish its process for determining compliance for analytes that have limits/water quality standards at a level lower than that which can be detected and/or quantified.

5. For a list of analytes as defined by EPA, the permit shall require that the Laboratory Detection Limit and the Laboratory Quantitation Limit be determined using the steps of the 40 CFR Part 136 procedure to establish the lowest possible value by the laboratory;

6. That EPA require the Laboratory Detection Limit and the Laboratory Quantitation Limit and the Permit Quantitation Limit be reported by the regulator to the Integrated Compliance Information System (ICIS).

The committee then voted on the recommendation but did not reach consensus.

Use #5 Setting Permit Conditions, Reporting and Using Data, and Determining Compliance When the Water Quality Based Effluent Limit (WQBEL) is Less Then Detection and Quantitation Capabilities of Existing Methods

The FACDQ recommends that EPA implement Section #5 of the Uses Document as follows:

Recommendation: The FACDQ recommends that the following recommendations be incorporated into 40 CFR Part 122, as appropriate.

Vote*: 12 Agree (Dave A., Bob A., Tom M., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Mary S.***), 4 Not Opposed (***Tim F., Richard B., Nan. T., Cary J.***), 4 Disagree (***Steve B., Michael M., Rick R., Barry S.***) (9-21-07)**

NOT APPROVED

The committee assigned Mary Smith and Dave Akers to write the majority report and Michael Murray, Steve Bonde and Rick Rediske to write the minority report. The points for each were as follows:

Majority Rationale

- Section is drafted, ok to send comments to them

Minority Rationale

- Focus on zero for averaging

Several members of the committee expressed frustration after this vote, saying they thought they were voting on the Uses as a "package," not one recommendation at a time. Later it was proposed that #5 be included with the other Uses, with a note that the committee had not reached consensus on it. The majority and minority reports would follow, to explain the rationales for the votes. It was suggested that the Final Report Work Group decide how to present Uses.

Matrix Effects (15 Green Dots, 3 Yellow Dots, 2 Red Dots)

Ms. Smith explained why EPA had placed a red dot. Major concerns included the significant amount of work EPA had committed to do (guidance document, regulations, programs, etc.). She said she thought this was likely to be difficult to draft and to develop a "one size fits all" approach. She also expressed concern about developing a document that would be prescriptive that would work for EPA and for the states.

Mr. Jackson added an explanation for the red dot he had placed. He said that matrix effects generally showed up in a specific industrial wastewater, not from a municipality. When one needs to deal with this issue, it generally requires working with the regulator to remediate the problem through alternative methods (Tier One process or state-approved methods). This proposal, he said, did not consider alternative approaches.

Mr. Pletl responded that in municipal programs with pre-treatment programs, the municipalities were the regulators. He said that the Public Utility caucus had raised this at the first meeting and said it was extremely important for that caucus. It feels that EPA should dedicate resources to this issue and address it properly.

Mr. Burrows said his concern was that it could be a potential barrier to getting new methods approved in Part 136, including methods that would address matrix effects. Mr. LaFleur responded that many of the methods in Part 136 could handle nothing but reagent water. New proposed methods should be tested to see if they do a better job.

Mr. Mugan agreed that the problem was a real one and it would be valuable to have better guidance in this area.

Mr. Pletl commented that earlier EPA had asked that many methods be tested for other matrices. Ms. Smith said that she had asked that question during a Policy Work Group call. She said that proponents of the recommendation assumed that this would affect one or two industries but it would be applied across the board, whether matrix effects are an issue or not, and raise QLs. She said that EPA also did not want to take on the whole world; it had to look at resource burdens.

Mr. Pletl said that he read this only as validation, to see if it worked in matrices other than DI water, not as raising the QL. Mr. LaFleur said that it had been left intentionally vague. If there were a guidance document and protocols on how to document and develop an industry-specific QL, then we could submit data. He said he felt the burden would not be on EPA; EPA could ask public utilities and industries to provide the data. Currently, there is no mechanism for this. Ms. Smith said that there were matrix effects concepts in Use #5; she said the agency was not trying to pretend matrix effects do not exist.

Ultimately, the committee developed four different recommendations to address matrix effects, in a search for consensus. The committee did not reach consensus on any of the four recommendations.

Recommendation #1

The FACDQ recommends that EPA publish new guidance on matrix effects. At a minimum, the guidance should outline the appropriate level of matrix effects validation necessary for method promulgation for analytical methods to be considered for 40 CFR Part 136. The FACDQ recommends that EPA adhere to this guidance in methods it develops and validates for promulgation in 40 CFR Part 136. This guidance should also address the following:

- Determining the appropriate number of matrices to take into account.
- The level of validation required verses the proposed scope of use for the analytical method.
- Matrix effects validation in the ATP program.
- Impacts for consensus standards methods considered for part 136.

Vote*: 10 Agree (*Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., David K., Jim P., Barry S.*), 7 Not Opposed (*Dave A., Bob A., Tim F., Tom M., Cary J., Michael M., Rick R.*), 3 Disagree (*Steve B., Richard B., Mary S.*) *(9-21-07)

NOT APPROVED

Recommendation #2

The FACDQ recommends that EPA develop a consistent protocol on how to demonstrate matrix effects. The FACDQ believes such a protocol should be sensitive to cost and required level of effort to ensure that it is applied consistently. Questions to be addressed by the protocol:

- What level of effort is necessary to determine if the matrix effects can be resolved by modifications of the analytical method that are within the flexibility allowed within the method?
- What set of experiments and data interpretation framework would suffice to demonstrate a matrix effect if performed properly?
- Who should be responsible for implementing a procedure to determine a matrix specific QL?
- How broadly applicable shall a matrix effect be considered? What level of demonstration should be considered adequate for a single facility? What level of demonstration should be undertaken to extend the matrix specific QL to other like wastewaters?

Vote*: 13 Agree (*Dave A., Bob A., Tom M., Richard B., Nan T., Roger C., Larry L., Dave P., John P., Zonetta E., Chris H., Jim P., Rick R.*), 6 Not Opposed (*Tim F., Steve B., Cary J., David K., Michael M., Barry S.*), 1 Disagree (*Mary S.*) *(9-21-07)

NOT APPROVED

Recommendation #3

The FACDQ recommends that EPA develop a procedure for determining matrix-specific detection or quantitation limits for use where appropriate. Again, such a protocol should be sensitive to cost and required level of effort.

Questions that should be addressed include:

- Who should be responsible for implementing a procedure to determine a matrix specific QL?
- How broadly applicable shall a matrix effect be considered?
  What level of demonstration should be considered adequate for a single facility?
  What level of demonstration should be undertaken to extend the matrix specific QL to other like wastewaters?

Vote*: 11 Agree (*Dave A., Tom M., Richard B., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., Jim P.*), 8 Not Opposed (*Bob A., Tim F., Steve B., Cary J., David K., Michael M., Rick R., Barry S.*), 1 Disagree (*Mary S.*) *(9-21-07)

NOT APPROVED

Recommendation #4

When considering future updates of QL_{nat}, the FACDQ recommends that EPA take into consideration any experience with the performance in different matrices when considering a revision of the QL_{nat}.

Vote*: 11 Agree (*Dave A., Tom M., Richard B., Nan T., Roger C., Larry L., John P., Dave P., Zonetta E., Chris H., Jim P.*), 4 Not Opposed (*David K., Michael M., Rick R., Barry S.*), 5 Disagree (*Bob A., Tim F., Steve B., Cary J., Mary S.*) *(9-21-07)

NOT APPROVED

The committee assigned Larry LaFleur, Jim Pletl and Zonetta English to write the majority report and Mary Smith, Bob Avery, Tim Fitzpatrick, Steve Bonde and Richard Burrows to write the minority report. The points for the minority report were as follows:

Minority Rationale

- EPA doesn't want to commit to the resources this would take at this time.
- It's also difficult. Seems we'd have a different QLnat for a small subset of industries that would raise the QLs for everyone else.
- It's impractical to ask EPA to respond to all data that come in indicating that matrix effects are an issue.

- Each wastewater can have different matrices. It's opening Pandora's box; every outfall could require its own QL.
- Concern about things that could be an obstacle to getting methods into Part 136.

Verification

(General opinion: 2 Green Dots, 2 Yellow Dots, 2 Red Dots)

(Alternative 1: 7 Green Dots)

(Alternative 2: 5 Green Dots, 5 Yellow Dots)

The committee discussed how and where to incorporate a recommendation on verification into the Final Report. The committee concluded that it made sense to use the verification recommendation as a resource document for majority report for the Single-Lab procedure rather than having it as a stand-alone recommendation.

The committee voted on this recommendation and reached consensus.

Verification Recommendation
The FACDQ recommends that the Verification Document be used as a resource document for the Single Lab DL QL Procedure v2.4 majority/minority report.
***Vote*: 18 Agree, 2 Not Opposed (*Zonetta E., Chris H.*), 0 Disagree** *(9-21-07)*
APPROVED

Implementation

Ms. Thomey proposed a next step. In light of the fact that the committee had not reached consensus on a procedure, she proposed the following recommendation for the committee's consideration:

> Although the FACDQ did not reach consensus on a procedure, the FACDQ recommends that EPA act to develop an alternative procedure to the current 40 CFR, Part 136, Appendix B procedure. The results of the pilot study and our evaluation of the ACIL-modified procedure indicate that there are deficiencies in the current 40 CFR Part 136 Appendix B procedure than can and should be corrected. The Single Lab DL/QL Procedure version 2.4 submitted contains elements that would be valuable to the agency in developing a new procedure.

The committee voted on the proposed recommendation and agreed by consensus.

Recommendation #1
Although the FACDQ did not reach consensus on a procedure, we recommend that EPA act to develop an alternative to the current 40 CFR Part 136 Appendix B procedure. The results of the pilot study, and our evaluation of the ACIL modified procedure, indicate that there are deficiencies in the current 40 CFR Part 136 Appendix B procedure that can and should be corrected. The Single Lab DL QL Procedure v2.4 submitted contains elements that would be valuable to the agency in developing a new procedure.
***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-21-07)*
APPROVED

EPA Guidance and Outreach Materials

Ms. Smith acknowledged that the committee had not reached consensus on the details of implementation but she asked if the committee wanted to recommend that EPA develop guidance and provide education. This became the basis for a new recommendation that read as follows: The FACDQ recommends that EPA develop guidance and outreach materials for stakeholders as they implement FACDQ recommendations.

The committee voted on this recommendation and reached consensus.

Recommendation #2
The FACDQ recommends that EPA develop guidance and outreach materials for stakeholders as EPA implements the FACDQ recommendations.
***Vote*: 20 Agree, 0 Not Opposed, 0 Disagree** *(9-21-07)*
APPROVED

Definitions Recommendations: Adding IUPAC Definitions to the Glossary

Mr. Phillips proposed a new recommendation as follows:

The FACDQ recommends that the IUPAC definitions for Lc, Ld and Lq be added to the glossary of the

report.

The committee discussed this proposal, asking why this step was needed, what the glossary would be used for, and if the terms would be used in the Final Report (yes for some majority/minority reports). Ms. English said that if definitions were needed, then it was up to the writer to supply them for the reader and to cite appropriately.

The committee voted on this recommendation and approved it by consensus.

Recommendation #1
The FACDQ recommends adding the IUPAC L_C, L_D, and L_Q definitions into the glossary.
Vote*: 13 Agree, 6 Not Opposed (*Bob A., Tim F., Tom M., Richard B., Cary J., David K.*), 0 Disagree, 1 Absent (*Dave A.*) *(9-21-07)
APPROVED

Definitions of Detection

The "working definitions" for Detection and Quantitation that the committee agreed to in 2005 were projected on a screen before the committee. Changes to the language were made on screen, so everyone knew what was being considered (and later, voted on).

The committee had a significant discussion about what was needed in the way of definitions for the Final Report and for the readers of the report. It also discussed the differences between the definitions (layman's and statistical).

After finalizing the recommendation on definitions for Detection, the committee voted and reached consensus.

Definitions: Detection Limits

The FACDQ recommends that the definitions for Detection Limits below be adopted for use in the Final Report:

DETECTION LIMIT (DL) – LAYPERSON'S DEFINITIONS

1. ***Detection Limit (DL) -*** *The minimum result which can be reliably discriminated from a blank (for example, with a 99% confidence level).*
2. **Detection Limit (DL)** – The lowest result that can be distinguished from the blank at a chosen level, α, of statistical confidence.

DETECTION LIMIT (DL) - STATISTICAL DEFINITIONS

1. **Detection Limit (DL)** - Smallest measured amount or concentration of analyte in a sample that gives rise to a Type I error tolerance of alpha under the null hypothesis that the true amount or concentration of analyte in the sample is equal to that of a blank. (The alternative hypothesis is that the true amount or concentration of analyte is greater than that of a blank.)
2. **Detection Limit (DL)** - The minimum observed result such that the lower 100 $(1-\alpha)$% confidence limit on the result is greater than the mean of the method blanks.

Vote*: 12 Agree, 7 Not Opposed (*Steve B., Cary J., Zonetta E., Chris H., David K., Jim P., Mary S.*), 0 Disagree, 1 Absent (*Barry S.*) *(9-21-07)

APPROVED

Definitions of Quantitation

The committee proceeded to consider definitions of Quantitation. After a show of hands on the choices indicated that no single Definition for Quantitation would be approved by consensus, Mr. Burrows suggested that QL and QL_{lab} should have different definitions.

The committee finalized the language of the recommendation, voted on the recommendation and reached consensus.

Definitions: Quantitation Limits
The FACDQ recommends that the definitions for Quantitation Limits below be adopted for use in the Final Report:

QUANTITATION LIMIT (QL) - DEFINITIONS

1. **Quantitation Limit (QL)**: The smallest detectable concentration of analyte greater than the detection limit (DL) where the accuracy (precision & bias) achieves the objectives of the intended purpose.
2. **Lab Quantitation Limit (QL_{Lab})**: The smallest detectable concentration of analyte greater than the detection limit (DL) where the accuracy (precision & bias) demonstrated by the laboratory achieves the objectives of the intended purpose.

***Vote*: 3 Agree (*John P., Rick R., Mary S.*), 16 Not Opposed, 0 Disagree, 1 Absent (*Barry S.*)** *(9-21-07)*

APPROVED

Final Report

Mr. Wheeler called on Ms. English to give a report on the process and schedule that the Final Report Work Group had developed during its 7:15 AM meeting to prepare the Final Report. Because the time between the September and December meetings was short and the workload significant, she asked that the committee review and approve the process and schedule as a formal recommendation. The process and schedule were projected before the committee as she spoke.

The committee agreed that the Final Report would be longer than the earlier target of 40 pages because of the addition of majority/minority reports. However, the committee still felt it was important to be concise and suggested the report be no more than 60 pages. Members raised a series of procedural and practical questions, including:

Majority/Minority Reports

- Maximum length of majority/minority reports. After discussion, it was agreed that authors should aim for one page; or, if they feel more is needed, they should notify the lead author for that chapter in advance.

- Identification of perspectives: It was agreed that individuals could be associated with their perspectives in these reports.

- Placement in the Final Report: It was agreed that the reports will follow the appropriate decision in

the body of the report.

Decisions to be incorporated into the Final Report

- Ms. Smith suggested that the section leads on the Final Report Work Group should cull through the comprehensive list of decisions (provided by Triangle Associates) and see which ones should come forward. Mr. LaFleur also suggested that members who have issues they strongly wanted to bring forward should contact the section lead.

Expectations for the Appendices

- It was agreed that consensus and non-consensus documents will be included in the Appendices provided they were identified appropriately.

Public Comment

- It was suggested that a list of those who spoke during the Public Comment period be acknowledged in a list and the reader should be directed to the docket.

Location of Issues/Recommendations Based on Decisions at the Meeting

- It was suggested that discussion of Matrix Effects and Verification should go into the chapter on the procedure.

- Uses document: Because of decisions made at this meeting, the Uses document which had earlier been represented "as a package" no longer includes all of the earlier components. It was suggested that the "Uses package" as approved appear in the body of the report with an explanation of the changes that occurred as a result of the decisions made (i.e., #1-3 were moved to other parts of the report; #4 was revised prior to approval; #5 was revised but was not approved by consensus; and #6-8 were unchanged). The draft package as it was brought to Meeting #10 would be presented in the Appendix as a "non-consensus" document.

The committee then voted on the Final Report recommendation and approved it by consensus.

Final Report Recommendation

The FACDQ approves the proposed process and schedule below for the Final Report of the Committee's work.

- The lead for each section will work with the designated back-ups to draft that section.
- The Final Report Work Group has some discretion over what goes into the appendices.
- As soon as a section is drafted, the lead will circulate it electronically to the caucuses for review and comment on a quick turn-around basis.
- Reviewers will be asked to send their comments on the initial draft via "tracked changes."
- The drafting team for each section will address those comments to the extent possible, accepting or rejecting the comments or making appropriate revisions, eliminating the "tracked changes."
- Before sending the draft to the Final Report Work Group, the lead will highlight any unresolved issues for Final Report Work Group discussion in **bold** type.
- The Uses Document was not a consensus document and it should be indicated as such in the main report with majority/minority perspectives.
- The Uses Document will be modified and included in the Appendix and will reflect the decisions made at the 10th FACDQ Meeting prior to being presented for a vote:
    - Moving Uses #1-#3 outside of the document.
    - The edits made on #4 prior to being voted on.
    - The edits to #5 prior to being voted on.

Proposed Schedule

- October 5: Majority/Minority Reports due to leads for the relevant section in the report
- November 9: Final Report Work Group sends first draft to the committee
- November 19: Submit comments back to Final Report Group.
- November 30: Final Report Work Group sends revised draft to the committee.
-

Details

- Use Microsoft Word, Times New Roman, font size 12
- Put section number and name in footer with the date of the draft (not autodates)

Assignments

Mr. Wheeler briefly reviewed the assignments from the meeting which included up to two additional

meetings of the Technical Work Group to work on a batch-specific verification option to bring as an informational product to the December meeting. It was agreed that it would not be a formal recommendation and that no committee vote would be taken.

Public Comment

Mr. Reding announced the public comment period however there was no comment at this time.

Wrap-Up

Ms. Smith thanked everyone on behalf of Michael Shapiro, Deputy Assistant Administrator for the Office of Water, and Ephraim King, Director of the Office of Science and Technology, and, from the heart, she added her thanks. She said that the red dots did not mean that EPA would ignore the majority opinions. The agency, she said, might need more time but those issues would still be on the table for EPA.

Mr. Reding adjourned the meeting at 2:45 PM.

11/21/2007

Draft for Discussion

Document # FACDQ11-03

MEETING ATTENDANCE

Committee Member Affiliation

Environmental Community

Michael Murray National Wildlife Federation

Richard Rediske Grand Valley State University

Barry Sulkin Environmental Consultant

Environmental Laboratories

Steve Bonde Battelle

Richard Burrows TestAmerica Laboratories

Cary Jackson HACH Company

(via teleconference)

Nan Thomey Environmental Chemistry, Inc

Industry

Roger Claff American Petroleum Institute

Larry LaFleur National Council for Air and Stream Improvement

John Phillips Alliance of Auto Manufacturers (Ford Motor Co.)

David Piller Exelon Corp.

States

Dave Akers Colorado Dept of Public Health and Environment

Bob Avery Michigan Dept of Environmental Quality

Timothy Fitzpatrick Florida Dept of Environmental Protection

Thomas Mugan Wisconsin Dept of Natural Resources

Public Utilities

Zonetta English Louisville/Jefferson Co Metropolitan Sewer District

David Kimbrough Castaic Lake Water Agency

Jim Pletl Hampton Roads Sanitation District

EPA

Mary Smith US Environmental Protection Agency

Designated Federal Officer

Richard Reding US Environmental Protection Agency

Facilitators

Alice Shorett Triangle Associates, Inc.

Bob Wheeler Triangle Associates, Inc.

Vicki King Triangle Associates, Inc.

Cole Gainer Triangle Associates, Inc.

Observers

Meredith Benedict US Environmental Protection Agency

Deb Dalton US Environmental Protection Agency

Brian Englert US Environmental Protection Agency

Terry Fenton US Environmental Protection Agency

Meghan Hessenauer US Environmental Protection Agency

Marion Kelly US Environmental Protection Agency

Nicole Shao US Environmental Protection Agency

11/21/2007

Draft for Discussion

Document # FACDQ11-03

Brad Venner US Environmental Protection Agency

Lemuel Walker US Environmental Protection Agency

Steve Wendelken US Environmental Protection Agency

Shen-Yi Yang US Environmental Protection Agency

Marcus Zobrist US Environmental Protection Agency

Kenneth Miller CSC, Inc.

Richard Witt OGC

Jim Christman Hunton & Williams

11/21/2007

Draft for Discussion

Document # FACDQ11-03

DISTRIBUTED MATERIALS

Committee's Packet of Materials

01. Draft Agenda FACDQ#10 8-31-07

02. Draft FACDQ Mtg Sum #7

03. Draft FACDQ Mtg Sum #8

04. Draft FACDQ Mtg Sum #9

05. Draft Revised Uses 8-31-07

06. Matrix Effects 8-31-07

07. Verification Recommendations

08. Implementation Timeline

09. Implementation Process Schematic

10. Implementation Guidance and Education

11. Implementation Recommendations

12. Additional FACDQ Recommendations

13. DQFAC Single Lab DL-QL Procedure Version 2.4

14. Questions et al re DQ FAC Single Lab DL-QL Proced

15. DevelopQL-for-National Use

16. REVISED Defns for Det and Quant

17. Target MQO Bounds

18. Groundrules Amendment

19. Decisions List for Members Use